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Highlights

The Possibility of Ambulatory

Maternal Well-Being during Pregnancy

Discovering Thoughts, Inventing Future

VOLUME 20 ISSUE 8 VERSION 1.0

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Maternal Well-Being during Pregnancy after One and Three Months from Delivery

By Fiorentino Nicoletta & Nardi Emanuele

Abstract- *Introduction:* Post-delivery depression damages neo-mothers, children and families alike. The specifically organized perinatal interventions are still few.

Objective: Evaluating the maternal well-being inside an *Innovative Training during Pregnancy and Post-Delivery,* and comparing EPDS and PHQ9 tests among Italian women.

Materials and Methods: An *innovative training* was experimented upon a randomized, controlled group of Italian women between 2011-2013. The results were measured with structured interviews, clinical folders, tests: SF36, EPDS, PHQ9.

Results: SF36 gives out significant domains. EPDS and PHQ9 are relevant within 3 months in the *Training* group and in the comparison among Italian women. Clinical analysis underlines convenient differences between the two groups.

Conclusions: The *Training* had a positive influence on the Post-Delivery Depression, suggesting new aid mods.

Keywords: *well-being, pregnancy, postnatal depression, training, EPDS, PHQ9, SF36.*

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Maternal Well-Being during Pregnancy after One and Three Months from Delivery

Studio Del Benessere Materno in Gravidanza, Ad Un Mese E A Tre Mesi Dal Parto

Fiorentino Nicoletta [α] & Nardi Emanuele [σ]

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I. Premessa Filosofico-Letteraria

La complessità del mondo, per essere più facilmente comprensibile, viene spesso affrontata per categorie che appaiono disgiunte e/o contrapposte le une alle altre.

Tali nette categorizzazioni, se da un lato risultano vantaggiose per l'organizzazione professionale del lavoro e delle risorse, dall'altra possono trarre in inganno e limitare la possibilità di azione e la loro completezza, sia a livello del singolo che della società.

Schopenhauer[1] diceva che non siamo "teste alate", esseri di pura idealità staccati dalle contingenze materiali in virtù di non meglio precisati favoritismi religiosi, spronandoci ad assumerci la responsabilità della nostra vita considerandola come quello che è: un amalgama sublime di materialità e cognizione, il cui benessere dipende dalla stabilità dell'equilibrio psico-fisico di questi due, imprescindibili, elementi.

Il filosofo tedesco non è stato l'unico a pensare una tale armonia, ma gran parte della più venerabile tradizione del pensiero antico (classico) e moderno (Nietzsche) concorda con lui su questo punto.

L'attento osservatore scientifico della realtà avverte che spesso l'essere umano agisce in diretta contraddizione con questa Verità, procurando così infelicità a se stesso ed imprecisione nei propri schemi di conoscenza.

I motivi di questa condotta sono molteplici, e non sono solo sussumibili al moralismo ma anche alla limitatezza della mente umana, costretta dalla sua finitudine a selezionare ed analizzare solo una limitata quantità del mare di informazioni con cui l'ambiente naturale la circonda, e a derivare verso la settorializzazione di nozioni e sapienza, al fine di cercare delle risposte alle nuove richieste derivanti dalla dinamicità della vita organica.

Se essa è davvero presente, è chiaro che la Verità riguardo la nostra natura, biologica o psicologica che sia, non può che pervenire a noi tramite un lungo e periglioso lavoro di ricerca e verifica, di dubbio e sperimentazione, di fatica e di vittoria innanzitutto sulla nostra limitata conoscenza.

In questa ricerca è stata effettuata l'analisi di importanti autori della letteratura scientifica, per verificare l'attendibilità delle fonti di base di questa sperimentazione, partendo dalla seguente domanda: quanto può influire il versante psico cognitivo coniugato con una controllata attività fisica sul benessere materno fetale e sull'evento nascita in quanto tale?

Nel rispondere a questa domanda, è inevitabile porre il proprio sguardo indagatore verso uno dei sintomi più evidenti della mancanza di benessere nella donna del periodo perinatale, ovvero la depressione.

Ed in questo complesso ambito di studi, già Hendrick (1998) affermava che la depressione post natale fosse il risultato di interazioni fra fattori fisici (cambiamenti ormonali, vulnerabilità genetica) e fattori psico-cognitivi (stress ambientali, "grandi eventi della vita" individuale della paziente). Tante altre voci si sono levate nel mondo scientifico per evidenziare il fatto che, nei Paesi in cui la depressione post natale è più alta (Brasile, Corea, Italia) la maggiore vulnerabilità biologica delle donne risulta strettamente connessa a fattori trans-culturali, psico-sociali e socio-economici. Tutti fattori

Author α: Ph.D Prenatal Medicine, via San Celso, 4 Bracciano (Rome), Italy.
Author σ: Philosopher, via San Celso, 4 Bracciano (Rome), Italy.
e-mail: e.nardi@yahoo.it

1 Cfr. Arthur Schopenhauer, *Il mondo come volontà e rappresentazione*, Mondadori, Milano, 1992, libro II, paragrafo 18, pp. 137-138.

extra-biologici, che insieme a quelli strettamente biologici influenzano il complesso processo della maternità.

Ciò premesso, una figura assistenziale, come l'ostetrica animata da autentica volontà di aiuto interpersonale, deve indirizzare il proprio sforzo verso le donne non solo in senso tecnico ed esecutivo, in quanto sostenuta dalle proprie conoscenze e competenze per influire sulla macchina biologica, ma con uno sforzo a tutto tondo, fornendo un supporto personalizzato e adeguato alla singola donna, teso a rafforzarle l'autostima ed a sorreggerne il senso di sicurezza, e facilitare così l'intenso e laborioso evento della nascita.

Questo studio rimarca e dimostra che è possibile integrare sincreticamente l'attenzione ad aspetti definiti qualitativamente con elementi quantitativi, offrendo così una completezza assistenziale.

Dopotutto, l'inferenza di fattori psicologico-comportamentali all'interno della depressione post natale sono oramai noti da tempo: fra di essi non vi sono solamente lo stress da accudimento ed il temperamento del neonato, ma anche altri elementi come ad esempio la stabilità dei rapporti di coppia, o altre caratteristiche contingenti.

Questi stessi fattori, adeguatamente studiati attraverso questionari come SF36, EPDS e PHQ9 e messi in relazione con le singole condizioni cliniche, si sono dimostrati fondamentali nello stabilire lo stato psico-fisico della gravida prima e neo-mamma dopo.

Questo studio vuole dimostrare il sorprendente potere lenitivo e di empowerment di strategie di sostegno specialistico non invasive sul benessere fisico della donna, pre e post partum, e sperimentare direttamente metodologie innovative di azione sulla depressione già in gravidanza.

La dimostrazione scientifica di queste asserzioni è lasciata al prosieguo della lettura di questo articolo; ciononostante, risulta essenziale riportare la isometria tra la tesi di questo testo e l'espressione letterario-filosofica di specifiche immagini tratte da alcuni tra i più grandi capolavori della letteratura mondiale, e ciò per una semplice ragione: esse costituiscono un preventivo studio qualitativo della questione, e possono facilitare agevolmente la mente del lettore nella comprensione delle conseguenze operative inerenti la concezione di un assistenzialismo ostetrico/scientifico più empatico e psicologico, "su misura".

Il modello scelto ad esempio per una visione assistenziale più vicina alla condizione umana della gravida, è rintracciabile nel romanzo *"Gli Indemoniati"* (1868) di Fëdor Dostoevskij.

In questo romanzo a sfondo politico di grande intensità, accade che, sebbene al termine della trama, uno dei protagonisti, il contadino Satov, riceva nel cuore della notte una visita inattesa: sua moglie Marjia Ignatijevna, che lo aveva precedentemente abbandonato in favore delle più affascinanti lusinghe del nobile Nikolaj Stavrogin, carissimo amico di lui. Ella si ritrova a chiedergli ospitalità per la notte, con il fare aggressivo ed affilato di chi pretende un favore ad un individuo pur consapevole che questi potrebbe legittimamente chiedergli soddisfazione per un torto passato.

Ed infatti la vergogna viene a malapena nascosta dalla fierezza dei forti lineamenti di Marija, mentre ribadisce al marito che la disturberà per poco tempo, e che passato il gelo della notte se ne andrà, da sola, a cercare un impiego nella misera, anonima città russa zarista in cui è ambientata la vicenda. Ma Satov nota subito qualcosa che non va: ella è affaticata, malferma nei passi e di estrema debolezza in tutto il suo muoversi, suda freddo. Improvvisamente, la Verità balza agli occhi dell'uomo: ella sta per dare alla luce il figlio illegittimo dell'amico Stavrogin, proprio lì in casa sua! Marija crede che egli andrà in collera, sentendosi truffato e gabbato al contempo, ma non è così: anni di studi universitari in Svizzera hanno sviluppato la già grande sensibilità di Satov, che riconosce nel parto il mistero cristiano ortodosso della nascita, ed in se stesso la figura imprescindibile e capitale di marito e di neo padre del nascituro.

Ma Satov non è solo un romantico idealista: e così l'uomo, in fretta e furia, vende quel poco che ha di valore nella sua stamberga per potersi permettere i servigi di Arìna Pròchorovna, l'ostetrica del luogo, rinomata per la sua eccellenza nella scienza medica ed, al contempo, il suo carattere spietatamente caustico e sarcastico nei confronti delle gravide, che si diverte a dileggiare proprio nei cruciali momenti del travaglio e del parto.

Arìna accorre in casa di Satov, e fa il lavoro per cui è stata pagata: con la sua usuale boria ed il suo carattere oltremodo difficile, aiuta la povera Marija ad espletare il proprio compito biologico. Ma finito il momento dell'azione, l'ostetrica si ferma ad osservare il puro, sincero amore di Satov nel prendersi cura della sua nuova famiglia; tale visione di schietta solidarietà provoca in lei, per contrapposto, una sprezzante reazione di scherno, ed un malriposto senso di superiorità che la induce a restituire il compenso nelle mani di Satov, sbeffeggiandolo per la sua ingenuità. La scena si chiude con l'acida ostetrica che, sghignazzante, se ne torna a casa propria, mentre, indaffarato ma felicissimo, il contadino provvede con inusitata energia ai fabbisogno della propria ritrovata famiglia.[2]

La descrizione di una tra le parti più coinvolgenti dell'intera opera dostoevskiana non può lasciare indifferenti, così come non può che risultare evidente la profonda pragmaticità scientifica del messaggio morale

2 Cfr. Fëdor Dostoevskij, *Gli Indemoniati,* Gherardo Casini Editore, Jugoslavia, 1990, pp. 535-548

ivi espresso. Infatti, la figura della beffarda Arìna, con il proprio sapere specificatamente tecnico, non viene unilateralmente sminuita da Dostoevskij, che, al contrario, ne mette in mostra la precisa efficienza e l'incrollabile sangue freddo come virtù operative fondamentali all'atto della nascita. Tuttavia, pari dignità letteraria e semantica viene riservata allo stesso Satov, il quale, quasi comprovando con la sua condotta la tesi di questo studio, migliora sensibilmente l'ambiente perinatale, aiutando in ogni modo la propria moglie prima con la solerzia del suo intervento economico, e poi con la calda fermezza del suo affetto coniugale che, quasi da solo, riesce a riscaldare un freddo stambugio russo ed a trasformarlo, con zelo ed ingegnosa perizia, in un ambiente atto ad accogliere la venuta di una nuova vita.

Un conseguimento che, nelle tragiche condizioni socio-economiche della Russia zarista, possiede un che di meraviglioso e sorprendente, e che per il realismo dell'immagine trasmessaci non può che farci domandare se questo evidente "progresso" inerente la nascita e l'accudimento parentale non sia a maggior ragione possibile e desiderabile nelle prassi assistenziali del nostro odierno, "progredito" Occidente.

II. Introduzione

La maternità è caratterizzata da una complessa transizione biologica, emotiva e sociale.

Essa si rivela come un'esperienza soddisfacente e psicologicamente positiva nella maggior parte delle donne (Fleming, et al., 1990; Green e Kafetsios, 1997).

Tuttavia, a volte risultano aumentati anche l'avvilimento, le frustrazioni, l'ansia, la confusione, (Born, et al., 2004) che, nel post partum, possono sfumare in multiformi varietà di sindromi emotive e/o in importanti malattie psichiatriche (Ugarizza e Robinson, 1997; Suri e Burt, 1997).

In Italia, le donne che sviluppano ogni anno una depressione perinatale sono 90.000, e circa il 40% delle donne che presentano depressione post partum hanno manifestato stati depressivi durante la gravidanza[3].

Precisata da Cox e Holden nel 2008, la definizione "depressione postnatale" (DPN), adottata anche in questa ricerca, è più ampia, in quanto descrive qualsiasi disturbo depressivo privo di aspetti psicotici nell'arco temporale compreso nel primo anno dopo il parto. Importante è distinguerlo dal *Maternity blues*, disturbo puerperale nelle primissime fasi successive al parto che coinvolge l'80% delle donne, (Gale & Harlow, 2003) e ritenuto il principale fattore di rischio di DPN (Block et al. ,2005).

Nel mondo occidentale, si ritiene che la DPN colpisca fra il 10 e il 15% delle donne che partoriscono (Breese McCoy, 2011, Buistet al., 2008; Gavin et al., 2005; Milgrom et al., 2005; Agostini et al., 2005; Greden, 2001; Evans et al., 2001; O'Hara & Swain, 1996), e che l'incidenza, pari al 6,8% raddoppi nelle madri adolescenti (Arnoldet al., 1999). Tuttavia, la prevalenza globale e l'ampiezza della DPN non sono sempre diagnosticati (Fisher, et al., 2012) e possono essere anche maggiori (Halbreich & Karkun, 2006).

La DPN è un obiettivo di intervento di Salute Pubblica sia per i danni che procura alle neo-mamme, sia per gli effetti negativi – immediati e/o a lungo termine – che ricadono sulla prole (Murray et al., 2003; Grace et al., 2003; Kavanaugh et al., 2006) e sull'intera struttura familiare (Martell, 1990; Boath et al., 1998).

Tuttavia, la DPN risulta ancora sottostimata, con conseguenti difficoltà nella rilevazione e nel trattamento (Parry, 2004).

Le difficoltà sono inoltre accentuate dalla scarsa richiesta spontanea di aiuto da parte della donna, che nonostante l'elevato livello di contatto con gli operatori sanitari durante gravidanza, parto e puerperio, non si interrelaziona come sarebbe auspicabile con i servizi offerti.

Dati recenti suggeriscono che la depressione è comune anche *durante* la gravidanza, non solo ne costituisce un fattore predittivo di DPN (Bowen, Muhajarine 2006; Dennis, Mc Queen, 2009) ma ne può rappresentare anche il logico *continuum*.

I disturbi mentali non vengono adeguatamente riconosciuti e trattati neppure durante la gravidanza (Marcus et al., 2003; Flynn et al., 2006, Marcus, 2009) e non sono coniugati con i fattori di rischio che sono sia biologici che psicosociali.

La letteratura scientifica annovera un cospicuo numero di ricerche tese a identificare i disturbi in gravidanza e post partum riferiti all'area psichica e psichiatrica; tuttavia pochi studi hanno orientato la loro attenzione nell'identificare interventi non invasivi, tesi cioè a favorire il benessere materno attraverso la promozione di corretti stili di vita e volti ad una continuità assistenziale che abbracci tutto il periodo perinatale.

Nella DPN, studi di efficacia hanno testato l'utilizzo della terapia cognitivo-comportamentale sia a livello individuale che di gruppo (Dennis & Hodnet, 2007; Milgromet al., 2005; Milgrom et al., 2003; Craig et al., 2005; Meager & Milgrom, 1996).

L'attività fisica regolare ha dimostrato di portare benefici segnalati per la madre e per il feto (Meltzer et al., 2010). Nonostante ciò, pochi interventi perinatali organizzati includono una attività fisica controllata ed abbinata alle normali cure assistenziali offerte.

III. Scopo Della Ricerca

a) Obiettivo primario

Valutare l'influenza sul benessere materno e sui disturbi riferibili a depressione, di un *Training innovativo*

3 Depressione perinatale: Conference call dell'Osservatorio Nazionale sulla salute della donna, 28 ottobre 2013

in gravidanza e post partum (ad un mese e a tre mesi dal parto), e confrontarla con il gruppo di controllo.

b) Obiettivi secondari

Eseguire l'analisi fattoriale dei test EPDS e PHQ 9, e fare la loro comparazione su donne italiane durante la gravidanza, ad 1 mese e 3 mesi dal parto.

c) Ipotesi di ricerca

In questo studio viene verificata l'ipotesi che partecipare ad un *Training innovativo ante e post partum* possa migliorare l'esito (outcome) riguardo ai disturbi riferibili a DPN, (depressione post natale) e migliorare quindi il benessere materno.

IV. Materiali e Metodi

Sono state reclutate 260 donne in gravidanza in un ambulatorio medico della provincia di Roma (Italia), tra aprile 2011 e maggio 2013.

Criterio di inclusione: gravidanza tra la 22^{a} e 24^{a} settimana di gestazione, in assenza di patologia materna e/o fetale.

Criteri di esclusione: età materna inferiore a 18 anni; presenza di disturbo di tipo depressivo e/o psichiatrico pregresso o in corso; gravidanza gemellare.

Le donne che hanno soddisfatto sia i criteri di inclusione che quelli di esclusione sono state 251. Nove donne (3,5%) sono state escluse dallo studio.

La valutazione dello stato di salute e della sintomatologia riferibile a depressione è stata effettuata:

- in gravidanza tra la 21^{a} e 24^{a} settimana di gestazione,
- ad 1 mese dal parto,
- e a 3 mesi dal parto,

mediante la somministrazione dei seguenti questionari: SF 36 (Short-Form 36 items Health Survey), EPDS (Edinburgh Postnatal Depression Scale) ed il PHQ 9 (Patient Health Questionnaire).

Attraverso una intervista individuale, sono stati reperiti i dati demografici, dalle cartelle i dati clinici della gravidanza, poi quelli del parto e del puerperio.

Le 251 gravide del campione sono state distribuite in due gruppi attraverso la randomizzazione.

Il gruppo di intervento denominato *Gruppo A*, costituito dal 44% di donne, ha ricevuto una conduzione medica della gravidanza ed il *Training*.

Il gruppo di controllo denominato *Gruppo B*, costituito dal 56% delle donne, ha seguito l'iter assistenziale standard con la sola gestione medica.

a) Raccolta dati dai questionari

Al momento dell'intervista, a 22-24 settimane di gravidanza, sono stati consegnati a tutte le donne iscritte alla ricerca i questionari SF 36, EPDS e PHQ 9.

Lo stesso procedimento è stato ripetuto ad 1 mese dal parto (in occasione della visita ginecologica di controllo), e successivamente a 3 mesi (in coincidenza della 1^{a} vaccinazione dei neonati).

Per valutare l'incidenza del *Maternity blues* é stata effettuata un'indagine pilota su un campione casuale del 10% indagato a 3-4 gg. dal parto utilizzando gli stessi strumenti e le stesse modalità del campione finale.

b) Descrizione degli strumenti

Le misure di qualità di vita relative alla salute vengono sempre più utilizzate nella ricerca ma anche nelle indagini sulla popolazione generale, nella pratica clinica e nelle valutazioni di politica sanitaria (Ware & Sherbourne, 1992).

I fattori che hanno favorito il loro utilizzo come indicatori sanitari scaturiscono dai cambiamenti avvenuti con l'evoluzione della medicina, che ha trasformato il decorso di diverse malattie da acuto a cronico, andando ad influire sul tempo delle cure, prolungandolo e inevitabilmente protraendo anche il contatto del paziente con la struttura sanitaria e gli operatori sanitari. Alle misure negative quali mortalità, morbosità o misure fisiopatologiche, si sono aggiunte lo stato di salute generale e quello percepito a livello individuale, la qualità di vita, il grado di soddisfazione delle cure ricevute e l'appropriatezza degli interventi sanitari.

Inoltre, dagli ultimi dieci anni di ricerca e applicazione pratica di questi strumenti, da una parte si è colto il punto di vista del soggetto come fonte unica ed attendibile di dati; e dall'altra è aumentata la disponibilità di strumenti validati, sempre più precisi ed accurati, capaci di raccogliere e trasformare l'opinione del paziente in informazioni preziose sia per il clinico che per il ricercatore.

La scelta degli strumenti si è orientata fra quelli validati e maggiormente utilizzati nella letteratura scientifica di riferimento, sono state ritenute particolarmente importanti per la agevole somministrazione a più soggetti contemporaneamente, la semplicità e brevità dei questionari, e per la siglatura e *scoring* facili da effettuare.

V. Il Questionario Short-form 36 Items Health Survey (SF 36)

L'SF36 è un questionario psicometrico multidimensionale che misura la *Qualità di vita* correlata alla Salute (Garrat et al. 2002). E' dimostrato (Stewart et al., 1989) che c'è coerenza interna per l'SF 36 sia nella popolazione generale (alpha di Cronbach >0,80), che nei sottogruppi svantaggiati (> 0,70) e nelle donne dopo il parto (> 0,70).

L'SF 36 è stato convalidato nelle donne in gravidanza e ha dimostrato di essere uno strumento affidabile sin dai primi mesi di gravidanza (Jomeen & Martin, 2005).

Mediante metodi psicometrici le informazioni raccolte sulle 8 scale di cui è composto, sono state

aggregate in 2 indici sintetici: uno pertinente al dominio fisico della salute Physical Component Summary (PCS 36) e l'altro a quello mentale Mental Component Summary (MCS 36).

Oggi, per le analisi quantitative della salute di specifiche popolazioni, tra le quali quella italiana (Apolone et al., 1997; Apolone & Mosconi, 1998) l'SF 36 può descrivere la salute percepita sia attraverso le 8 scale, sia con i 2 indici sintetici.

Le 36 domande si riferiscono concettualmente a 8 dimensioni di salute (Tabella 1).

Tabella 1: Domini SF 36. (adattato da Apolone, Mosconi, Ware, 1997)

Scale concettuali	*Sigle*	*Quesiti*	*Item*
Attività fisica	AF	10	3a,b,c,d,e,f,g,h,i,j
Ruolo e salute fisica	RSF	4	4
Dolore Fisico	DF	2	7,8
Salute generale	SG	5	1,11
Vitalità	VT	4	9a,e,g,i
Attività Sociali	AS	2	6,10
Ruolo e stato emotivo	RSE	3	5
Salute mentale	SM	5	9b,c,d,f,h

Nello specifico, oltre a scale di misura dello "star male" *(distress),* l'SF 36 contiene anche misure di salute positiva (Tabella 2).

Tabella 2: Domini SF 36 (adattato da Apolone, Mosconi, Ware, 1997)

		Fisica				*Mentale*			
Scale concettuali	*Sigle*	*Funzione*	*Benessere*	*Disabilità*	*Valutazione personale*	*Funzione*	*Benessere*	*Disabilità*	*Valutazione personale*
Attività fisica	AF	♦							
Ruolo e salute fisica	RSF			♦					
Dolore Fisico	DF		♦	♦					
Salute generale	SG				♦				♦
Vitalità	VT		♦				♦		
Attività Sociali	AS			♦				♦	
Ruolo e stato emotivo	RSE							♦	
Salute mentale	SM					♦	♦		

I domini sono così indicati:

AF- misura in cui la salute interferisce con diverse attività fisiche;

RSF– valuta i problemi con il lavoro/attività quotidiane a causa della salute fisica;

DF- valuta l'entità del dolore fisico e le limitazioni relative;

SG- è la valutazione personale di salute generale;

VT- fornisce la percezione del grado di stanchezza o di energia;

AT- indica la misura in cui la salute interferisce con le normali attività sociali;

RSE- riflette i problemi con il lavoro o altre attività a causa di problemi emotivi.

SM- riflette l'umore generale, il benessere psicologico, o l'angoscia.

Tutte le domande dell'SF 36, tranne una (item n°11), si riferiscono ad un periodo di quattro settimane antecedenti alla compilazione del questionario e le risposte alle domande sono segnate su una scala a 5 punti.

Questi punteggi assoluti, vengono poi trasformati in un punteggio (tra 0 e 100); i valori più alti indicano un livello superiore di benessere, il valore 100 rappresenta una salute ottimale.

In Italia, il questionario è stato tradotto ed adattato culturalmente a metà degli anni '90 nell'ambito del progetto International *Quality Of Life Assessment* (IQOLA).

Per avere uno strumento più sensibile a cambiamenti più recenti nello stato di salute, é stato elaborato un nuovo format, *SF 36 acuto*, modificando dalla forma standard il periodo di richiamo per sei delle otto scale [RSF, DF, VT, AS, RSE e SM] da "quattro settimane fa" a " la settimana scorsa " ed eliminando il periodo di richiamo nelle scale AF e SG.

Tutti gli altri elementi tra il modello acuto e standard sono rimasti identici.

Confronti e verifiche tra *SF 36 acuto* e SF 36 standard sono stati indagati e descritti ed hanno confermato che le risposte all'*SF 36 acuto* tendevano ad essere più reattive, con punteggi medi più elevati e correlati in base alla gravità della malattia.

In questo studio il format *SF 36 acuto* è stato utilizzato per il campione *Maternity blues*, di donne a 3-4 gg. dal parto adattando ulteriormente il periodo di richiamo "alla settimana in corso" ed eliminando il periodo di richiamo nelle scale AF e SG.

VI. L'edimburgh Postnatal Depression Scale (epds)

L'EPDS è stato ideato da John Cox e collaboratori nel 1987. Questionario di auto-valutazione di 10 item, è utilizzato in tutto il mondo per lo screening dei soggetti che presentano sintomi depressivi sia nei mesi successivi al parto che in gravidanza.

Il punteggio di codifica va da 0 a 3; e il riferimento temporale è l'ultimo mese.

Come suggerito da più lavori (Matthey, 2006) il cut-off è rappresentato dal punteggio ≥13 il quale indica la presenza di probabili sintomi depressivi.

Compilato dalle donne in pochi minuti; necessita della assenza di interferenze familiari o del ricercatore che possano influenzare le risposte della donna.

Lo scoring dell'EPDS , semplice e veloce, non richiede particolari conoscenze psichiatriche per l'interpretazione, pertanto, si presta molto per un uso di screening.

a) Analisi Fattoriale EPDS

Recentemente, diversi autori hanno studiato la struttura dell'EPDS e nonostante Cox e Holden (2003) affermino che il test EPDS non è stato progettato per misurare l'ansia, hanno trovato che questo strumento misura non solo la depressione post natale ma anche altre dimensioni, inclusa l'ansia.

Studi internazionali hanno effettuato le analisi fattoriali all'EPDS, mostrando che l'EPDS contiene due fattori (Adouard et al., 2005; Matthey, 2008) mentre altri autori (Brouwers et al., 2001; Ross et al., 2003; Jomeen & Martin, 2005; Montazeri et al., 2007; Tuohy & McVey, 2008) hanno trovato tre fattori, variamente identificati.

Tuttavia non c'è accordo sul numero e sull'identificazione dei fattori o sulle capacità delle varie dimensioni dello strumento di identificare le donne a rischio di DPN.

Al momento della definizione del disegno di ricerca e dopo la revisione della letteratura non sono stati reperiti studi di questo tipo effettuati su campioni di donne italiane.

VII. Il Patient Health Questionnaire 9 (PHQ 9)

Il Patient Health Questionnaire (PHQ 9) basato sui criteri del DSM-IV, viene usato sia in clinica che nella ricerca; sia come strumento diagnostico sia per valutare l'andamento dei sintomi in risposta ai trattamenti utilizzati.

Il PHQ9, elaborato nel 1990 possiede una validità diagnostica paragonabile a quella originale del PRIME-MD (valutazione delle cure primarie dei disturbi mentali) ma possiede una maggiore efficienza; è di facile e veloce compilazione, può essere utilizzata considerando la somma dei punteggi ottenuti ai vari item, e come scala per valutare la gravità della sintomatologia depressiva (Spitzer, Kroenke, Williams, 2001).

Il PHQ 9 è validato in campioni post partum (Gjerdingen et al., 2009; Weobong et al., 2009) lo hanno trovato altamente sensibile e specifico (92%).

Inoltre, un importante studio americano randomizzato controllato il TRIPPD, (Yawn et al., 2009), ha rilevato che il PHQ 9 risulta altrettanto valido dell'EPDS possedendo una buona concordanza nel rilevare le donne non a rischio di DPN.

Usato nel presente studio, ed al momento, non essendo stati reperiti ulteriori studi comparativi fra PHQ 9 ed EPDS, nella popolazione italiana, si è proceduto a raggiungere l'obiettivo secondario ovvero, confrontare i punteggi EPDS e PHQ 9.

A tale scopo si è utilizzata la tabella punteggi ed interpretazione dei due test reperita in letteratura dallo studio di Yawn, et al., 2009 per determinare in ogni donna la concordanza o discordanza negli EPDS e PHQ 9 (Tabella 3).

Intendendo per *concordanti* quando entrambi i punteggi sono "normali" o che entrambi i punteggi sono nelle singole categorie elevate; e *discordanti* quando uno è collocato nel range elevato e l'altro nel "normale".

Tabella 3: Categorie EPDS e PHQ 9 (adattato da Yawn, et al., 2009)

EPDS Punteggio	Interpretazione	PHQ 9	
		Punteggio	Interpretazione
0-9	"Normale"	0-4	"Normale"
10, 11	"Rischio lievemente aumentato"	5-9	"Lievi sintomi depressivi"
12-15	"Rischio aumentato"	10-14	"Sintomi depressivi moderati"
≥ 16	"Probabile Depressione"	≥ 15	"Da moderatamente grave a sintomi depressivi severi"

Le modalità di allattamento sono state indagate e classificate facendo riferimento alla classificazione WHO sull'alimentazione infantile (Tabella 4.)

Tabella 4: Allattamento: definizioni, tipologia

Definizioni	Tipo di ALLATTAMENTO	ALIMENTI Assunti
Allattamento materno ESCLUSIVO	SENO	*SOLO* Latte materno (LM) Latte materno spremuto (LMS) Latte materno donato (LMD)
Allattamento materno PREDOMINANTE		LM o LMS + Liquidi non nutritivi (H_2O/soluzione glucosata, tisane camomilla)
Allattamento materno PREDOMINANTE	MISTO	LM o LMS + Latte Artificiale
Alimentazione COMPLEMENTARE	ARTIFICIALE	No LM o LMS o LMD

a) *Descrizione dell'intervento sul Gruppo A (sperimentale)*

L'intervento condotto dal ricercatore-caregiver, si è sviluppato mediante l'azione su due ambiti di attività interconnessi: interventi psico educativi durante l'attività fisica.

L'intervento effettuato ha previsto un incontro settimanale di gruppo della durata di 1 ora, le donne che hanno partecipato hanno iniziato gli incontri tra la 22^a-24^a settimana di gravidanza e li hanno protratti fino al parto.

Durante il percorso, ed in base alla stagione, oltre agli incontri settimanali, ogni gruppo si è incontrato almeno una volta insieme ai propri mariti/compagni, e al cargiver-ricercatore in incontri organizzati al mare o a merenda o a cena.

A termine di gravidanza e durante il mese successivo al parto, tutte hanno potuto usufruire di consulenze telefoniche di sostegno da parte del caregiver-ricercatore.

Successivamente, dalla visita di controllo ad 1 mese dal parto, le donne hanno seguito 4 incontri al mese della durata di un'ora per un totale di 8 incontri fino al 3° mese dopo il parto, a cui partecipavano anche i neonati.

Il numero di donne partecipanti agli incontri non ha mai superato le 10 unità a seduta.

L'esercizio fisico è stato un importante mediatore fra le convinzioni/consuetudini popolari e personali nei confronti del benessere in gravidanza soprattutto in relazione alle barriere opposte allo sport, alle credenze popolari sull'alimentazione e riguardo alla suscettibilità percepita nei confronti della DPN e della sua rilevanza.

E' stato utilizzato come attrezzo di ginnastica dolce una palla personale, la palla svizzera, ed un tappetino personale.

Gli esercizi aerobici hanno riguardato la postura e il distretto del pavimento pelvico con esercizi di propriocezione riferiti alla loro funzione in gravidanza, durante il parto, nel post partum e nella vita quotidiana. L'obiettivo in gravidanza era mantenere il benessere fisico allenando i muscoli del pavimento pelvico a contenere e sostenere l'aumento ponderale della gravidanza.

Attraverso l'inserimento semplificato di elementi legati alla fisiologia della gravidanza, è stata suggerita l'interpretazione delle modificazioni fisiche come la naturale evoluzione della maternità fatta di cambiamenti necessari, modulabili dalla donna e contemporanei alla costruzione dell'assetto materno[1].

Le donne sono orientate ad una maggiore consapevolezza del proprio status, a non subirlo come un evento ineluttabile ed estraneo alla propria volontà, o addirittura dannoso per il proprio fisico.

Dalla 32^{a} settimana gli esercizi fisici erano tesi a far acquisire maggiori conoscenze sui tempi del travaglio-parto, sulle strutture coinvolte dal "transito" del feto; a riguardo le donne eseguivano degli esercizi fisici che coinvolgevano la muscolatura vaginale anche attraverso l'astrazione mentale.

In questo periodo si è fatta molto leva sull'assetto materno delle gravide stimolato e costruito durante la gravidanza.

Nel post partum l'orientamento degli esercizi fisici era di tipo riabilitativo, svolti in funzione della modalità di parto espletata.

Tecnicamente e come da protocollo strutturato, in gravidanza gli interventi hanno previsto una partecipazione attiva delle donne che settimanalmente avevano il compito di mantenere un Diario del Peso e della Pressione arteriosa, delle ore e del tipo di attività fisica svolta e l'annotazione di eventuali episodi importanti ("life stress event") rilevati nel corso della settimana.

L'approccio utilizzato nell'affrontare le diverse tematiche è stato volutamente intervallato da incontri strutturati ed incontri liberi e aperti alla personalizzazione; sempre associati ad attività fisica, ovvero durante lo svolgimento degli esercizi fisici le donne esprimevano i loro pensieri, le loro difficoltà e ne discutevano fra pari (counseling non direttivo).

Gli argomenti emersi, negli incontri successivi, venivano ricondotti alle indicazioni dettate dalla letteratura scientifica tramite un counseling direttivo da parte del cargiver-ricercatore a volte con l'ausilio di immagini e/o video.

Le donne, durante tutto il percorso sono sempre state invitate a verificare le fonti delle informazioni che ricevevano, ed esortate a valutarle non solo sulla loro esperienza personale ma in modo critico.

Il protocollo di intervento adottato per la sensibilizzazione a carattere psico educativo sulla

[1] Daniel N. Stern, N. Bruschweiler-Stern, "Nascita di una madre, come l'esperienza della maternità cambia la vita di una donna", Mondadori, Milano, 2000. ISBN: 88-04-48121-8 depressione ante- e post natale è stato strutturato seguendo le indicazioni fornite dagli studi clinici, dalle linee guida di riferimento e da interventi manualizzati ad indirizzo cognitivo comportamentale già utilizzati nella popolazione italiana e pubblicato da Piacentini et al., 2011.

VIII. Risultati

Dai dati anagrafici, il campione totale, costituito da 251 donne, risulta composto per il 97% da italiane, con mariti/compagni italiani nel 98% delle coppie.

L''80% delle donne sono coniugate, il 19% conviventi.

Il restante 1% è 'single'.

L'età media delle donne è di 32,5 anni (D.S. 4,5), quella dei padri risulta di 36 anni (D.S. 5,8).

In dettaglio, le classi e le rispettive frequenze sono descritte in Tabella 6.

Tabella 6: Età madri e padri

Classe d' età♀	%♀	%♂	Classe d' età ♂
21-26 anni	9,6	7,2	22-28 anni
27-32 anni	41	43	29-35 anni
33-38 anni	39,4	35	36-42 anni
39-42 anni	10	12,4	43-49 anni
		2,4	50-60 anni
Totale	100	100	Totale

Di seguito (Tabelle 7-10) sono riportate le frequenze delle variabili descrittive riferite al titolo di studio, alla professione, al tipo di occupazione, alla condizione economica e alla relazione affettiva delle coppie.

Tabella 7: Scolarità madri e padri

Titolo di studio ♀	%♀	%♂	Titolo di studio ♂
Licenza elementare	0,4	0,4	Licenza elementare
Licenza media	22,3	25,9	Licenza media
Diploma Scuola superiore	47	58,2	Diploma Scuola superiore
Diploma universitario	4,4		Diploma universitario
Laurea	25,1	15,5	Laurea
Dottorato di ricerca	0,8		Dottorato di ricerca
Totale	100	100	Totale

Tabella 8: Professione madri e padri

Professione ♀	%♀	%♂	Professione ♂
Casalinga	31	0,4	Pensionato
Operaia/colf	2,8	21	Operaio/cameriere
Commerciante/artigiana	2,4	9,2	Commerciante/artigiano
Impiegata/insegnante	41	47	Impiegato/insegnante
Libera prof.sta/ imprenditrice/dirigente	8	16	Libero prof.sta/ imprenditore/dirigente
Disoccupata	13	5	Disoccupato
Studentessa	1,6	0,8	Studente
Totale	**100**	**100**	**Totale**

Tabella 9: Occupazione madri

Occupazione ♀	%
Stabile	43
Precaria	17,5
Condizione non richiesta	39,5
Totale	100

Tabella 10: Condizione economica e Relazione affettiva della coppia

Condizione economica ♀♂	%	Relazione affettiva♀♂	%
Stabile	86	Stabile	94
Precaria	14	Precaria	6
Totale	100	Totale	100

a) Dati relativi alla gravidanza e al parto

Le donne erano primipare nel 66,5% dei casi, secondipare 32,3%, terzipare 1,2%.

Le gravidanze sono state controllate per il 98% in ambulatorio medico privato.

Le donne hanno definito la loro gravidanza "normale" per il 94%, e "a rischio" per il 6,4% (i rischi riferiti sono indicati nella Tabella 11).

Tabella 11: Tipologia di rischio in gravidanza

Tipologia di rischio in gravidanza	%
Patologia materna	2
Patologia fetale	1,6
Rottura prematura delle membrane (32w)	0,8
Minaccia di parto prematuro	1,2
Procreazione medicalmente assistita	0,8
Totale	6,4

Durante la gravidanza, il 12,7% delle donne ha eseguito 1-2 ecografie, il 69% 3-4 ecografie e il 18% 5-10 ecografie.

Il 48% delle donne ha assunto un integratore multivitaminico.

A fine gravidanza, le donne hanno avuto un aumento ponderale medio di 11,2 kg (D.S. 3,5). Nel 10% dei casi tale aumento era compreso tra 4 e 6,5 kg; nel 48%; tra 7 e 12,5 kg; nel 30% tra 13 e 15 kg, e nel 12,4% tra 16 e 22kg.

Il 19,9% delle secondipare e terzipare aveva seguito un corso di preparazione alla nascita durante la prima gravidanza.

Ha praticato attività sportiva suppletiva durante la gravidanza il 21% delle donne, non lo ha praticato il 72%; il 7% delle donne lo ha sospeso durante la gravidanza.

Il 45% del campione totale di gravide ha accettato di entrare nel gruppo di intervento tra la 24^a e la 26^a settimana di gravidanza.

b) Modalità di parto

L'87% delle donne ha partorito nel punto nascita della Asl di appartenenza. Il 2% delle donne che hanno partorito in Asl diverse ha fatto ricorso alla parto analgesia.

I parti vaginali sono stati il 67,7% (operativi l'1,6%, con episiotomia il 61%) e i tagli cesarei sono stati il 32,3%.

L'età gestazionale media è stata di 39,4 settimane (D.S. 1,5); il 90% delle donne ha partorito tra la 36^a e la 41^a settimana, l'1,2% tra 33^a e 35^a e l'8,8% alla 42^a.

Il peso medio dei neonati era di 3,291 kg (D.S. 450); il 3,6% di essi aveva un peso compreso tra 1,890 e 2,470 kg; il 26,3% tra 2,500 e 3,050 kg; il 64% tra 3,060 e 3,980 kg; il 6% tra 4,000 e 5,090 kg.

Il 57,4% dei neonati era di sesso maschile, il 42,6%, di sesso femminile.

Gli indici di Apgar assegnati ai neonati e tratti dalle cartelle cliniche della gravidanza/parto sono riportati in Tabella 12.

Tabella 12: Indice di Apgar

Indice di Apgar	a 5 minuti	a 10 minuti
da 7 a 10	95,6%	98,4%
da 4 a 6	4,0%	1,6%
da 0 a 3	0,4%	
totale	100%	100%

Ad 1 mese dal parto, il 79% del campione totale allattava al seno (esclusivo per il 31% e predominante per il 69%) l'allattamento misto avveniva nel 5,2% dei casi; quello artificiale nel 16,3%. Al 3 mese continuava ad allattare al seno l'81% delle donne.

Le donne che hanno sospeso l'allattamento al seno hanno riferito le seguenti difficoltà (tra parentesi è riportata la frequenza): insufficiente produzione di latte (33%), problemi di salute materna (24%), difficoltà del neonato (14%), per scelta della donna (29%).

Nessuna delle donne del campione aveva mai sofferto di depressione (criterio di esclusione) mentre la depressione nei familiari (marito, madre, sorella/e, fratello/i, genitori, suoceri) era presente nel 5,4% (di questi, il 5,2% era in terapia).

c) Percezioni materne

Il 77% delle donne del campione totale dichiarano di aver "vissuto bene" la gravidanza, e il 23% "non bene"; il 78% di aver "vissuto positivamente" il travaglio e il parto e il 24% di aver avuto dei disagi.

Durante tutto il ricovero in ospedale, le donne hanno dichiarato di aver ricevuto il maggior sostegno dall'ostetrica nel 5,6% dei casi, dal ginecologo nel 13%, dall'intera equipe nel 6%, dai propri familiari nel 33,% mentre nel 42,6% non sono state percepite figure di rilievo ma la donna ha contato soprattutto su se stessa.
Il 51% del campione totale delle donne ha segnalato '*life stress events*' particolarmente rilevanti (Tabella 13).

Essi sono stati aggregati in 5 gruppi che comprendono:

1. Condizioni economiche e sociali (lavoro precario, licenziamento, difficoltà economiche);
2. Eventi legati alla gravidanza e al parto (minaccia di aborto, parto prematuro, parto operativo; gravidanza pregressa patologica e/o con patologie feto/neonatali, parto pregresso distocico);
3. Conflitti familiari e di coppia (conflitti con la famiglia d'origine e famiglia acquisita, instabilità di coppia);
4. Eventi sociali e familiari a valenza negativa (lutti, trasloco, lontananza per lavoro del marito/compagno);
5. Eventi sociali e familiari a valenza positiva (es. matrimonio, vacanze, acquisto casa, gravidanza desiderata).

Tabella 13: '*life stress events*'

'life stress events'	singolo	multiplo
1. Condizioni economiche/sociali negative	28%	65%
2. eventi ostetrici/neonatali	34%	3%
3. conflitti familiari/coppia	16%	17%
4. eventi socio familiari negativi	11%	12%
5. eventi socio familiari positivi	10%	3%
Totale	100%	100%

Correlazioni significative variabili socio demografiche e cliniche ed EPDS nel Gruppo A (Tabella 13a)

Tabella 13.a: Correlazioni

Correlazioni variabili socio demografiche e cliniche ed EPDS nel Gruppo A	
P=0.01	P=0,05
Life stress events a T1	Life stress events a T0
Familiari depressi a T1 e T2	Familiari depressi in terapia a T0
Familiari depressi in terapia a T1 e T2	Condizione professionale materna a T1 e T2
Tipo di allattamento a T1	Tipo di allattamento a T2
	Praticare sport, a T0

d) Analisi questionario SF 36

Per poter analizzare il questionario SF 36 si è proceduto a sviluppare gli 8 domini e i domini sintetici PCS e MCS sviluppandone le medie nel gruppo totale delle donne (251) a T0, T1 e T2 (Grafico1 e 2).

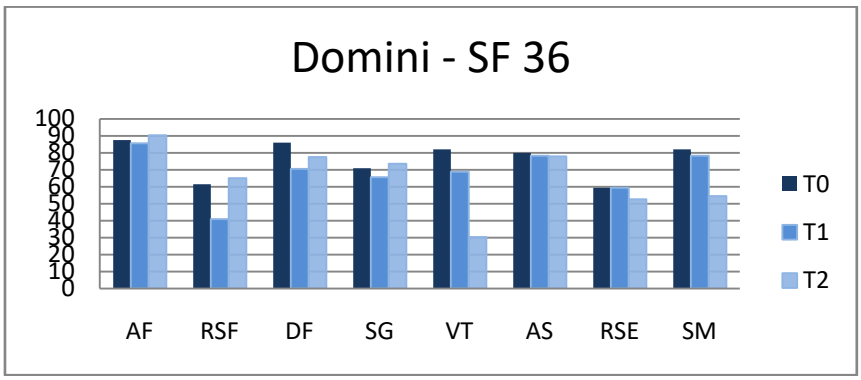

Grafico 1: Medie Domini SF 36 del campione totale

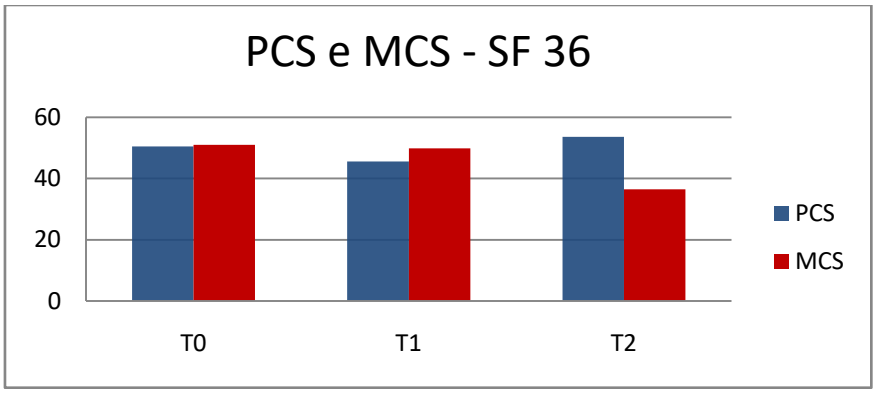

Grafico 2: Medie PCS e MCS del campione totale

Le medie dei singoli domini e degli indici sintetici sono stati messi in relazione a quattro classi d'età a T0, (Tabella 14.) a T1, (Tabella 15.) a T2 (Tabella 16.).

Tabella 14: Risultati SF 36 totali a T0 per classi d'età

Campione totale per classe Età a T0	21-26		27-32		33-38		39 42	
	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.
Attività fisica	91,04	10,00	88,59	8,44	86,11	9,78	85,80	10,87
Ruolo e salute fisica	66,67	29,18	62,86	36,19	58,59	33,34	63,00	34,70
Dolore fisico	90,92	15,40	85,45	18,55	85,17	19,38	87,28	18,65
Salute in generale	67,04	22,22	70,80	18,83	72,39	20,39	70,04	21,36
Vitalità	79,58	11,60	82,48	10,31	82,32	10,53	81,20	11,21
Attività sociali	81,25	14,28	80,22	16,00	80,43	14,85	76,00	16,89
Ruolo e stato emotivo	66,67	26,01	61,49	31,57	57,58	32,58	52,00	34,80
Salute mentale	83,17	20,36	83,61	15,64	81,21	18,98	78,40	21,26
PCS	51,23	4,63	50,40	6,12	50,17	5,58	51,24	6,69
MCS	51,41	8,81	51,63	7,93	50,88	8,71	48,53	9,89

Tabella 15: Risultati SF 36 totali a T1

Campione totale per classe Età a T1	21-26		27-32		33-38		39-42	
	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.
Attività fisica	89,35	11,63	87,06	9,95	84,37	12,18	81,00	14,72
Ruolo e salute fisica	42,71	34,17	45,15	35,02	36,62	34,31	39,00	39,58
Dolore fisico	73,92	19,73	71,74	21,24	68,01	20,23	72,88	21,94
Salute in generale	65,79	22,77	66,73	20,94	65,90	20,78	60,20	20,94
Vitalità	69,17	12,65	69,66	15,12	68,74	16,48	65,80	16,44
Attività sociali	81,77	15,19	79,00	15,38	77,65	14,86	74,50	16,72
Ruolo e stato emotivo	63,89	25,85	62,46	29,40	55,89	32,93	56,00	32,94
Salute mentale	80,33	20,15	80,35	16,10	77,37	19,61	71,68	22,74
PCS	46,35	5,74	46,09	6,94	44,84	6,84	45,08	6,63
MCS	50,92	8,72	50,69	8,04	49,50	9,38	47,36	10,18

Tabella 16: Risultati SF 36 totali a T2

Campione totale per classe Età a T2	21-26		27-32		33-38		39-42	
	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.
Attività fisica	93,54	8,01	90,49	8,24	90,05	8,28	87,80	12,75
Ruolo e salute fisica	68,75	33,17	65,53	32,30	64,39	32,56	63,00	37,58
Dolore fisico	78,50	17,85	78,63	20,19	75,17	17,90	81,76	18,84
Salute in generale	73,96	22,06	75,95	20,30	72,51	20,92	67,88	22,63
Vitalità	30,83	14,42	29,42	11,57	30,51	13,18	34,20	17,00
Attività sociali	80,21	20,82	80,83	22,47	76,26	22,12	70,00	26,27
Ruolo e stato emotivo	58,33	29,90	58,58	30,42	48,48	30,96	40,00	28,87
Salute mentale	53,17	6,40	54,65	7,63	54,07	7,11	56,48	8,35
PCS	54,58	6,29	53,73	6,00	53,33	6,09	53,35	7,32
MCS	36,73	4,75	37,48	5,22	35,83	5,23	35,07	4,52

Nei Grafici 1-3 sono riportati i domini fisici, mentali e totali del campione totale a T0, nei Grafici 4-6 a T1, nei Grafici 7-9 a T2.

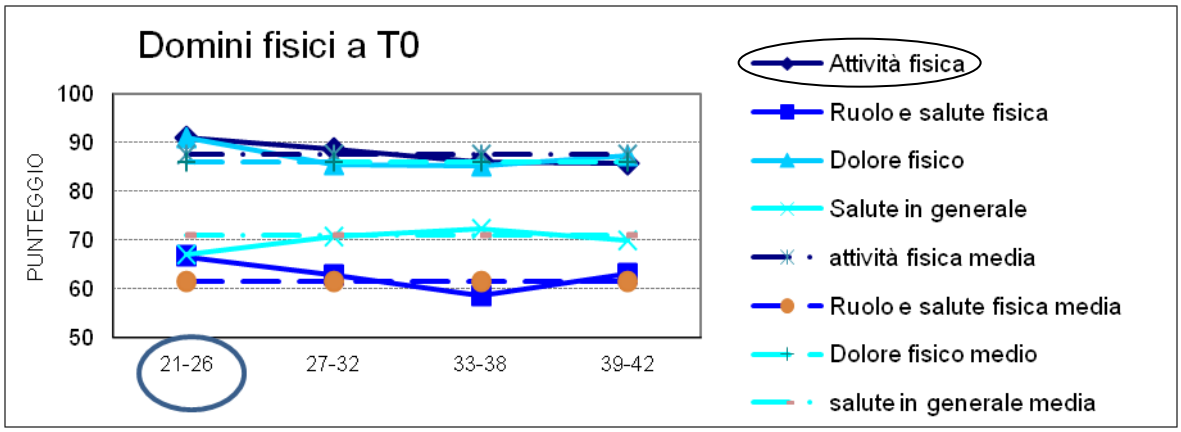

Grafico 1: Domini fisici in base all'età a T0

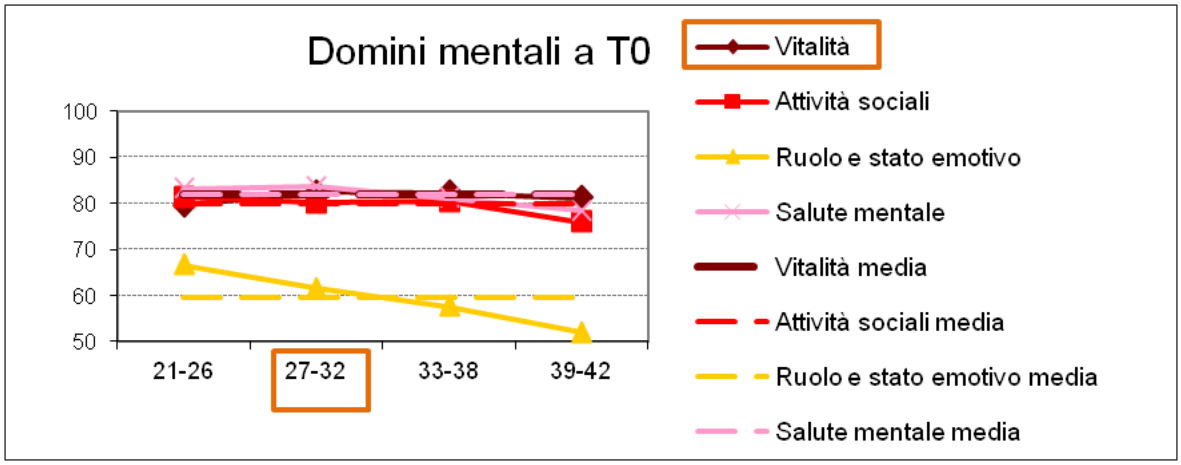

Grafico 2: Domini mentali in base all'età a T0

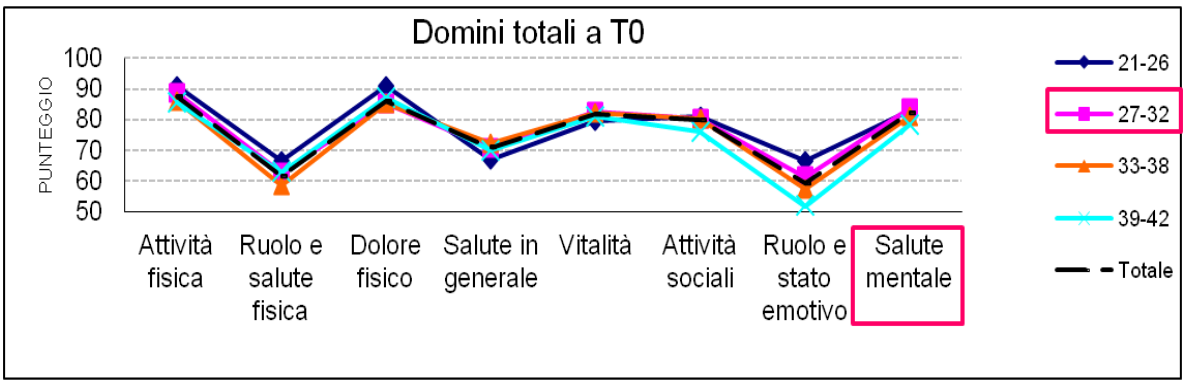

Grafico 3: Domini totali in base all'età a T0

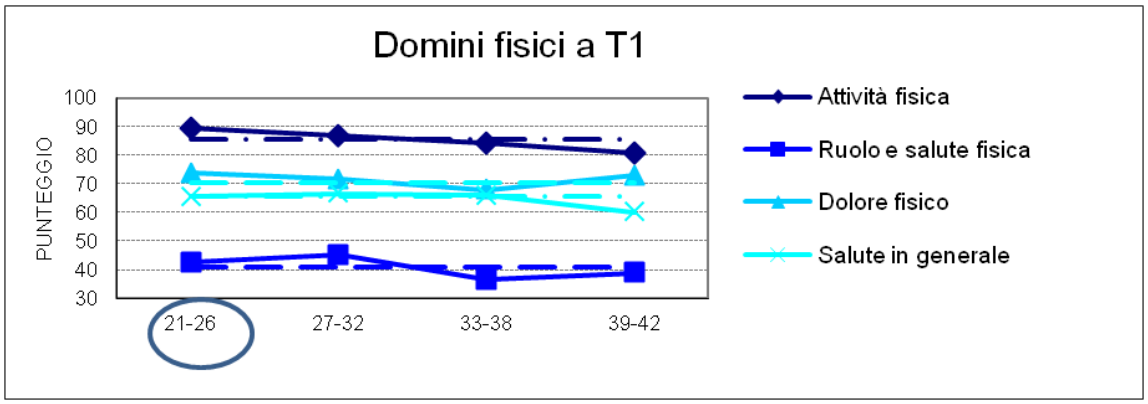

Grafico 4: Domini fisici in base all'età a T1

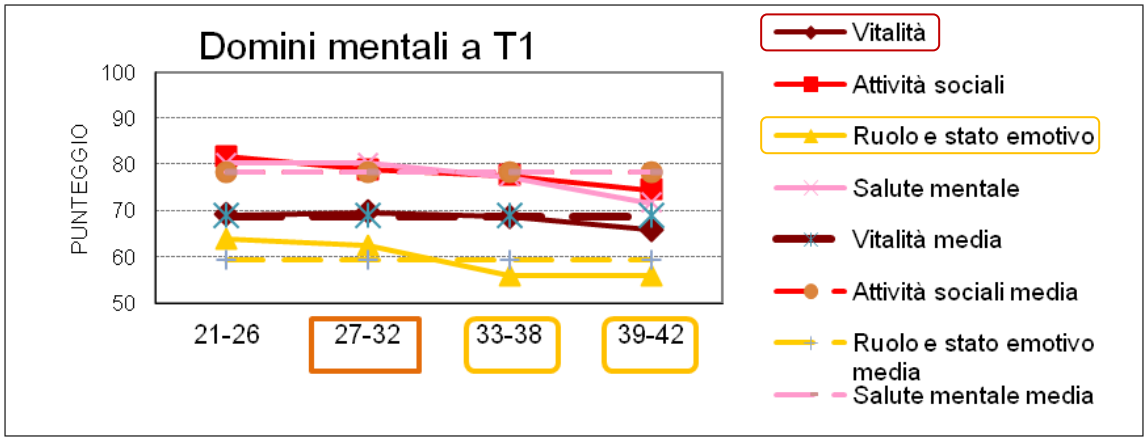

Grafico 5: Domini mentali in base all'età a T1

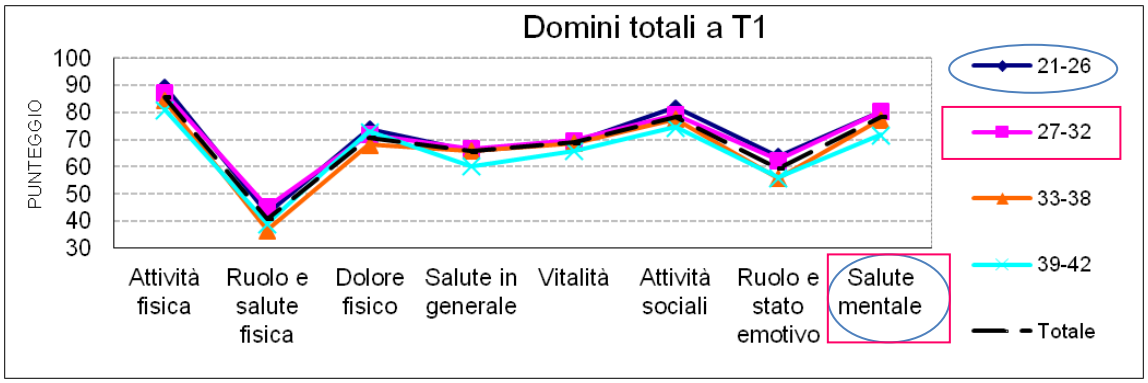

Grafico 6: Domini totali in base all'età a T1

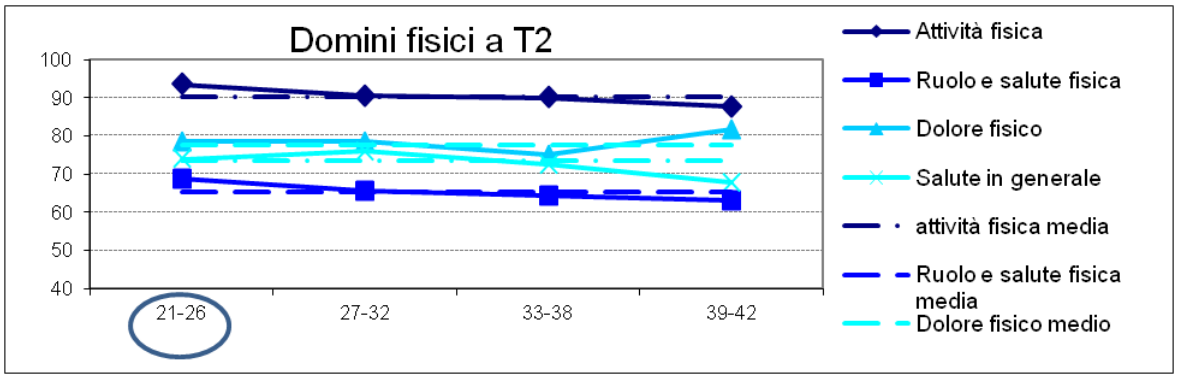

Grafico 7: Domini fisici in relazione all'età a T2

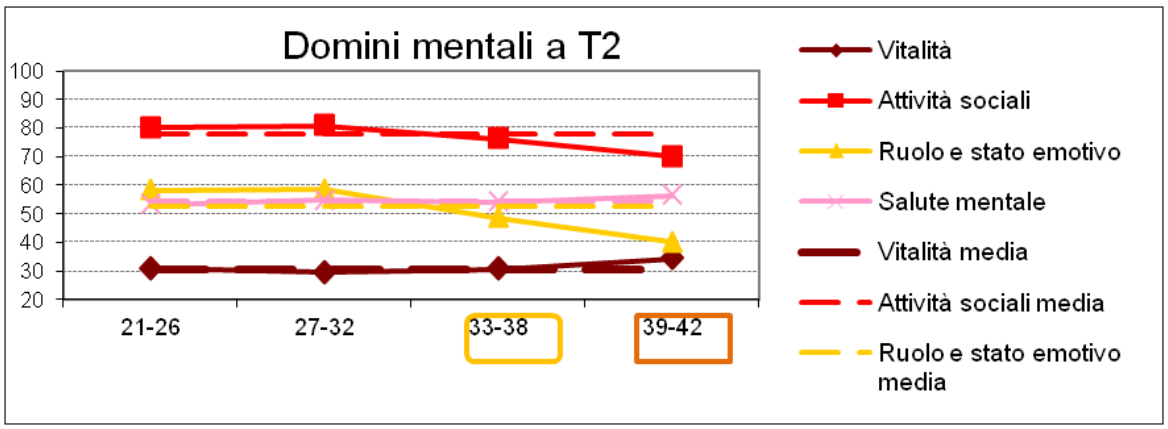

Grafico 8: Domini mentali in base all'età a T2

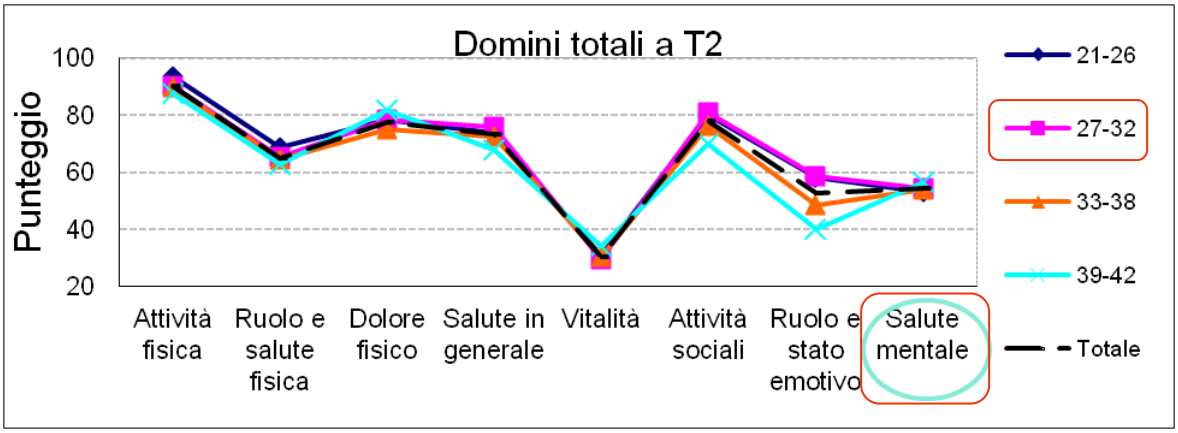

Grafico 9: Domini totali in base all'età a T2

e) *Risultati del confronto SF 36 fra il Gruppo A e il Gruppo B a T0,T1 e T2*

Per il confronto fra il Gruppo A e il Gruppo B sugli 8 domini e i due indici sintetici del questionario SF 36 ai tempi T0, T1e T2, si è utilizzato il test non parametrico U di Mann-Whitney a campioni indipendenti e ad un livello di significatività <0,05.

Si sono rilevate differenze tra i due gruppi nelle seguenti variabili:

- a T0 - attività fisica (p=0,007);
- a T1- PCS-36 (p=0,013), dolore fisico (p=0,036), salute in generale (p=0,000), vitalità (p=0,004), salute mentale (p=0,004);
- a T2 le variabili totali sono riportate nelle Tabelle 16-17 e nei Grafici 10-13.

Differenze SF 36 fra il Gruppo A e il Gruppo B a T2

Tabella 16: Risultati SF 36 totali - Gruppo A - a T2

Gruppo A Età	21-26		27-32		33-38		39-42		Totale	
	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.
Attività fisica	94,00	7,38	89,62	8,71	89,38	8,33	85,00	12,82	89,59	8,87
Ruolo e salute fisica	80,00	28,38	68,87	28,55	71,25	38,21	78,13	28,15	71,40	32,13
Dolore fisico	80,40	18,06	81,51	20,96	72,05	18,46	88,00	17,00	78,47	20,00
Salute in generale	89,50	7,55	82,53	16,79	85,05	15,59	84,00	13,82	84,17	15,50
Vitalità	22,00	7,53	27,64	9,59	26,38	11,60	26,88	7,53	26,62	10,09
Attività sociali	86,25	13,76	89,62	18,95	86,56	19,49	92,19	14,85	88,40	18,36
Ruolo e stato emotivo	76,67	22,50	65,41	29,21	62,50	29,42	45,83	30,54	63,96	29,18
Salute mentale	52,40	6,10	53,43	6,98	52,80	5,45	55,00	7,33	53,23	6,35
PCS	56,90	5,24	54,82	5,43	54,29	5,94	56,91	5,71	54,97	5,62
MCS	38,01	4,16	38,70	5,08	37,95	5,23	36,62	5,06	38,22	5,03

Tabella 17: Risultati SF 36 totali - Gruppo B - a T2

Gruppo B Età	21-26		27-32		33-38		39-42		Totale	
	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.	Media	D.S.
Attività fisica	93,21	8,68	91,40	7,70	90,51	8,29	89,12	12,90	90,93	8,77
Ruolo e salute fisica	60,71	34,96	62,00	35,80	59,75	27,47	55,88	40,05	60,18	32,70
Dolore fisico	77,14	18,26	75,58	19,07	77,29	17,34	78,82	19,42	76,85	18,15
Salute in generale	62,86	22,42	68,98	21,51	64,00	19,85	60,29	22,21	65,21	20,99
Vitalità	37,14	15,03	31,30	13,20	33,31	13,54	37,65	19,21	33,50	14,38
Attività sociali	75,89	24,25	71,50	22,31	69,28	21,19	59,56	24,02	69,55	22,40
Ruolo e stato emotivo	45,24	28,06	51,33	30,27	38,98	28,47	37,25	28,58	43,81	29,41
Salute mentale	53,71	6,79	55,94	8,13	54,93	7,97	57,18	8,92	55,44	8,01
PCS	52,93	6,63	52,58	6,40	52,67	6,15	51,68	7,54	52,54	6,40
MCS	35,82	5,09	36,19	5,11	34,39	4,75	34,34	4,20	35,17	4,88

A T2 nei Domini fisici, le differenze fra i due gruppi erano nelle seguenti variabili:

- ruolo e salute fisica (p=0,003),
- salute in generale (p=0,000).

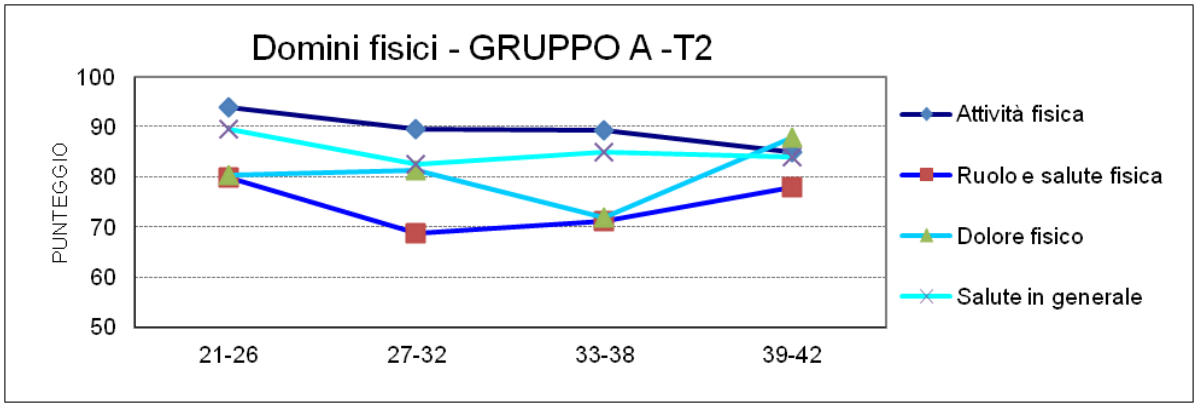

Grafico 10: Domini fisici in base all'età - Gruppo A - a T2

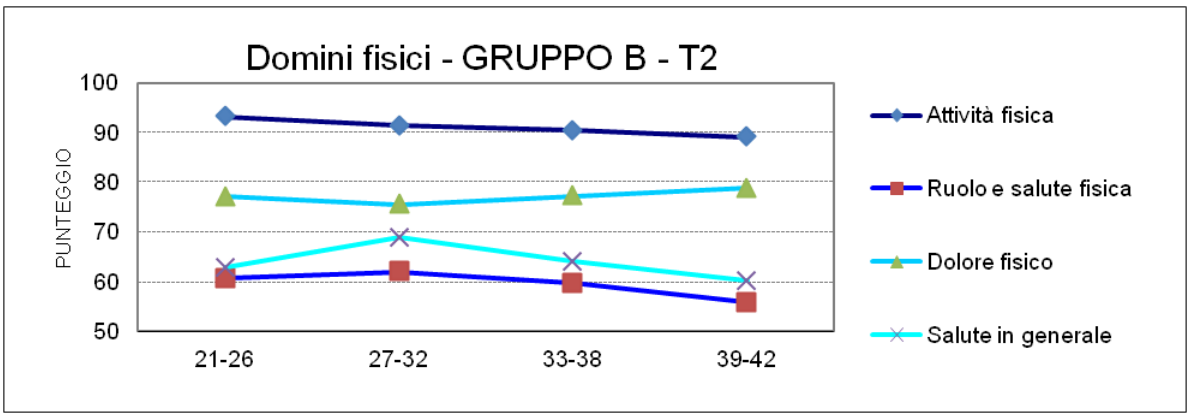

Grafico 11: Domini fisici in base all'età - Gruppo B - a T2

A T2, nei Domini mentali le differenze fra i due gruppi erano nelle seguenti variabili:

- vitalità (p=0,000),
- attività sociali (p=0,000),
- ruolo e stato emotivo (p=0,000).

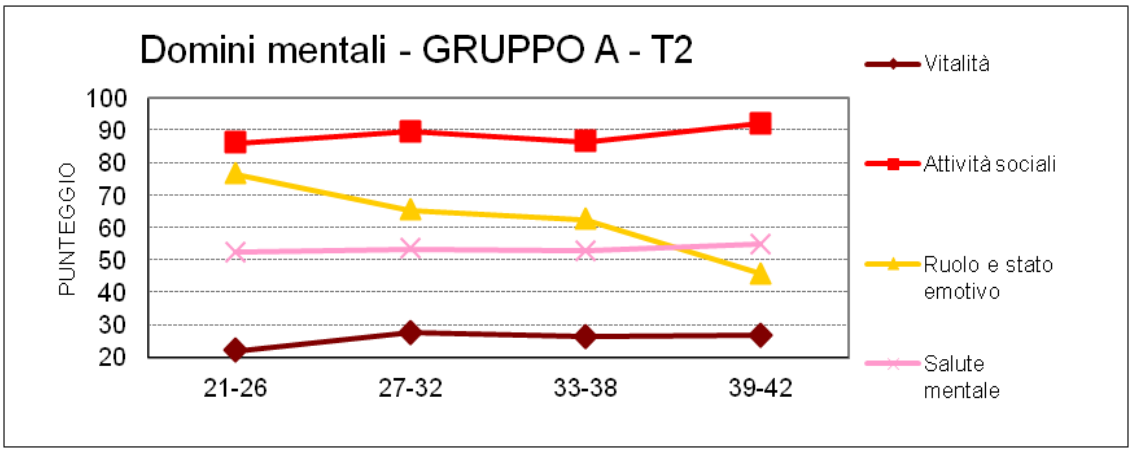

Grafico 12: Domini mentali in base all'età - Gruppo A - a T2

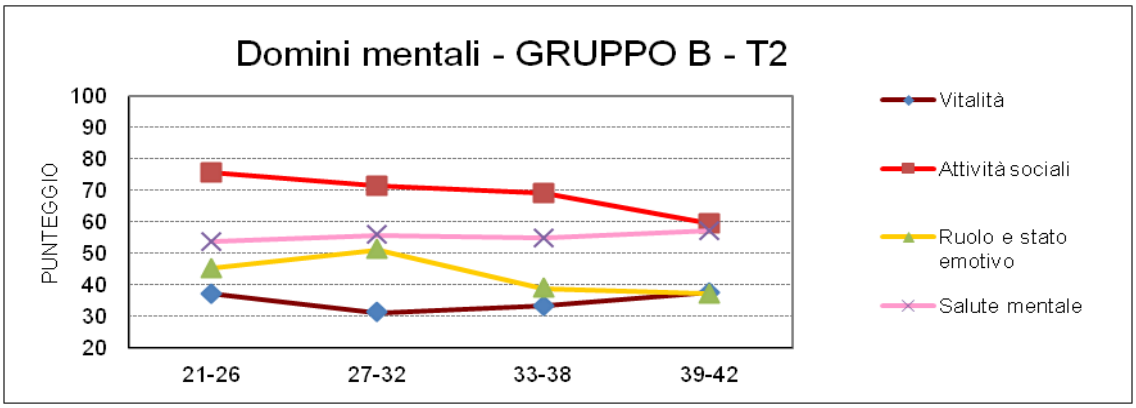

Grafico 13: Domini mentali in base all'età - Gruppo B - a T2

A T2 le differenze fra i due gruppi erano in entrambi i Domini sintetici PCS-36 (p=0,003) e MCS-36 (p=0,000).

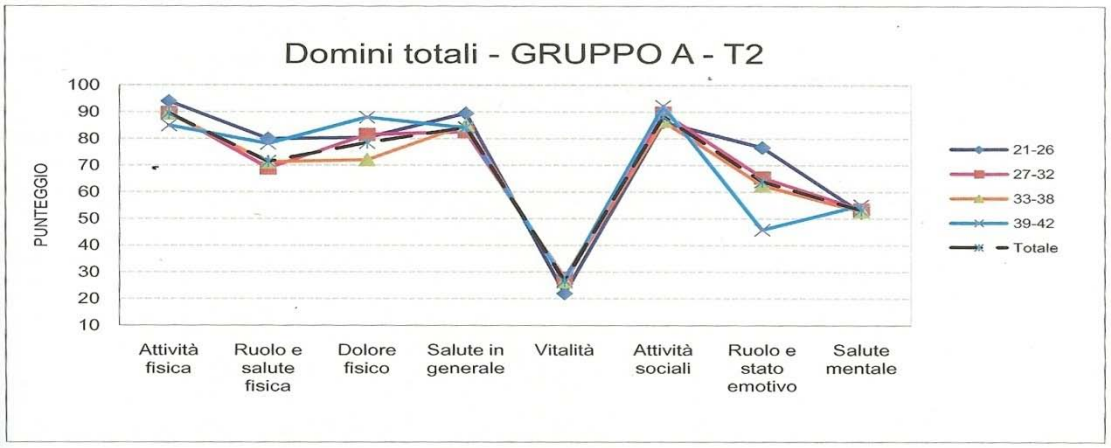

Grafico 14: Domini totali in base all'età - Gruppo A- a T2

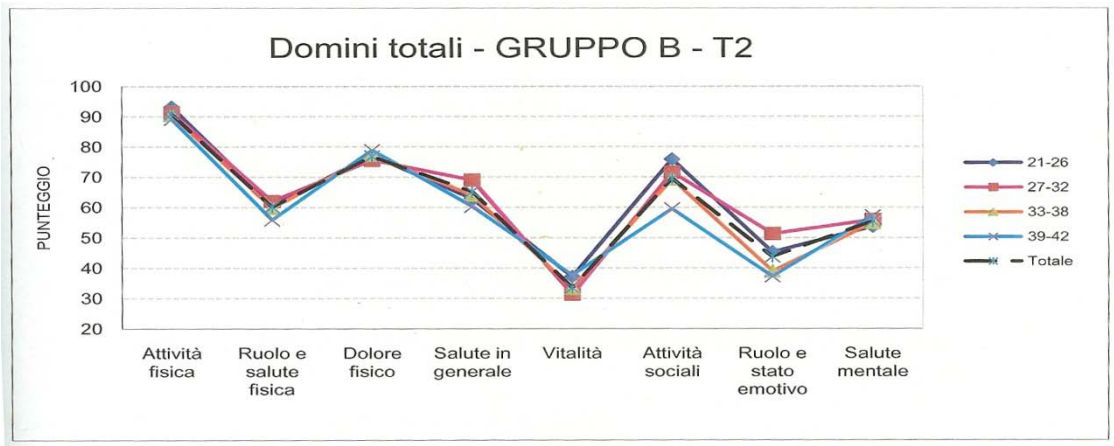

Grafico 15: Domini totali in base all'età - Gruppo B - a T2

f) Test EPDS

Nel confrontare i punteggi EPDS in gravidanza (T0), ad 1 mese dal parto (T1) e a 3 mesi dal parto (T2) si è utilizzato il test non parametrico per campione singolo (Kolmogorov-Smirnov).

g) Risultati positivi globali

Nel campione totale di 251 donne (♀) le percentuali del test EPDS positivo (cut-off ≥13 = positivo), sono le seguenti:

- a T0 è del 7%, n°18 ♀
- a T1 è del 9%, n°23 ♀
- a T2è dell'12%, n°29 ♀

Nel confrontare i punteggi EPDS a T0, T1 e T2 fra il Gruppo A d'intervento e il Gruppo B di controllo, si è utilizzato il test non parametrico U di Mann-Whitney a campioni indipendenti.

Nel Gruppo A si sono ottenuti i seguenti risultati:

- a T0 sono risultate positive all'EPDS, n°7 ♀ (cut-off positivo ≥13) = 6%
- a T1sono risultate positive all'EPDS, n°10 ♀(cut-off positivo ≥13) = 9%
- a T2sono risultate positive all'EPDS, n°4 ♀(cut-off positivo ≥13) = 4%

Nel Gruppo B si sono ottenuti i seguenti risultati:

- a T0 sono risultate positive all'EPDS, n°11♀(cut-off positivo ≥13) = 8%
- a T1 sono risultate positive all'EPDS, n°13♀(cut-off positivo ≥13) = 9%
- a T2 sono risultate positive all'EPDS, n°25♀(cut-off positivo ≥13) = 18%

Come risulta evidente dal Grafico 16, essere inclusi nel Gruppo A d'intervento incide positivamente a tre mesi

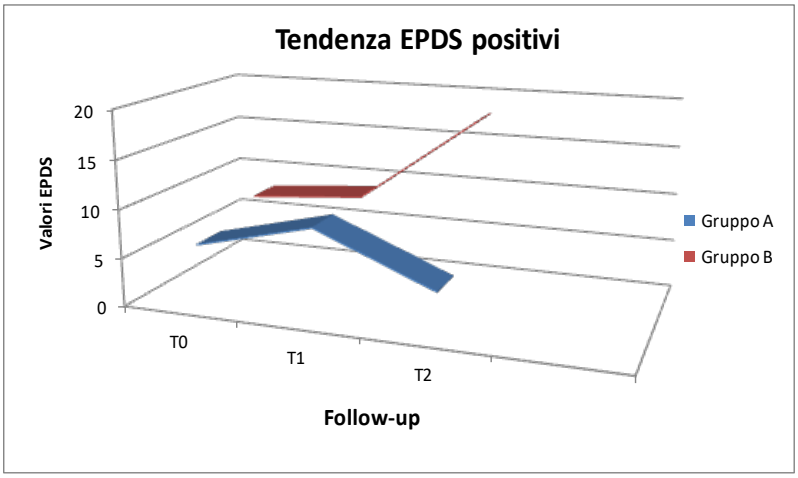

Grafico 16: Tendenza EPDS positivi a T0, T1, T2 nei due gruppi

h) Descrizione dei risultati PHQ 9

Risultati positivi globali

Nel campione totale di 251 ♀ le percentuali del test PHQ 9 positivo (cut-off ≥11 = positivo), sono le seguenti:

- T0 è del 6%, n°15 ♀
- a T1 è del 10%, n°24 ♀
- a T2 è dell'11%, n°27 ♀

Descrizione dei risultati PHQ 9 nei due gruppi a T0, T1 e T2

Nel Gruppo A si sono ottenuti i seguenti risultati:

- a T0 sono risultate positive del PHQ 9, n° 6♀ (cut-off positivo ≥11) = 5,4%
- a T1sono risultate positive del PHQ9, n° 9♀(cut-off positivo ≥11) =8,1%
- a T2sono risultate positive del PHQ9, n° 4♀(cut-off positivo<11) = 3,6 %

Nel Gruppo B si sono ottenuti i seguenti risultati:

- a T0 sono risultate positive del PHQ9, n° 9♀(cut-off positivo ≥11) =6,4%
- a T1sono risultate positive del PHQ9, n° 15♀(cut-off positivo ≥11) = 10,7%
- a T2sono risultate positive del PHQ9, n° 23♀(cut-off positivo ≥11) = 16,4%

L'essere inclusi nel Gruppo A d'intervento incide a tre mesi (Grafico 17).

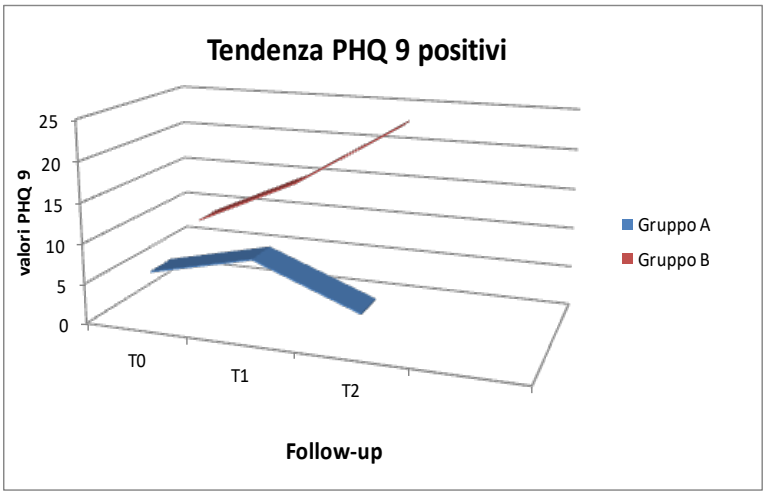

Grafico 17: Tendenza PHQ9 positivi a T0, T1, T2

i) Risultati test di concordanza EPDS e PHQ 9

Attraverso il test non parametrico U di Mann-Whitney a campioni indipendenti, risultano significativi ad un livello di 0,05 l'EPDS a T2 e il PHQ 9 a T2 confermandone la concordanza.

Tra i questionari EPDS e quelli PHQ 9 c'è correlazione in tutti e tre i tempi di follow-up (significatività pari a 0,01) (Tabella 18.)

Tabella 18: Risultati EPDS e PHQ 9 a T0, T1 e T2

EPDS SCORE	T0	T1	T2	PHQ 9 SCORE	T0	T1	T2
	n°♀				*n°♀*		
0-9	200	195	196	0-4	137	132	151
10, 11	25	25	18	5-9	85	85	67
12-15	21	24	26	10-14	26	29	28
≥ 16	5	7	11	≥ 15	3	5	5

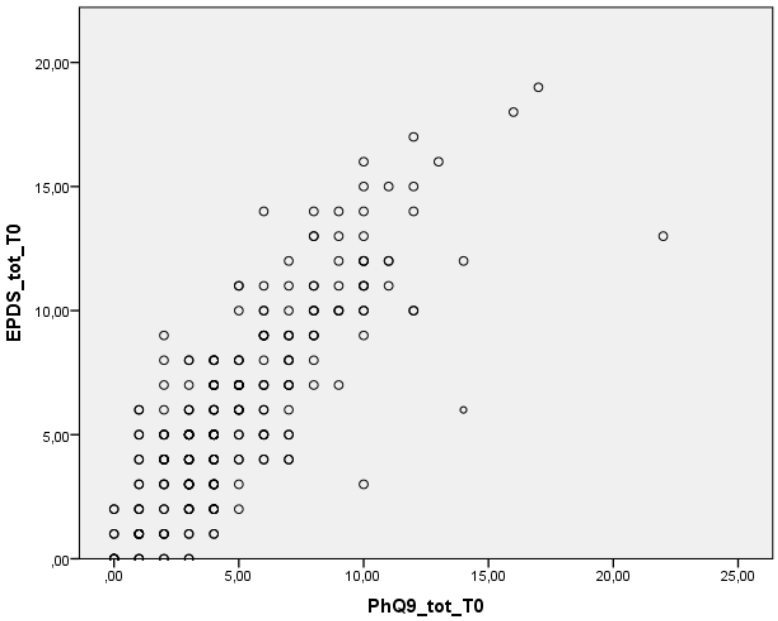

Grafico 18: EPDS e PHQ 9 a T0

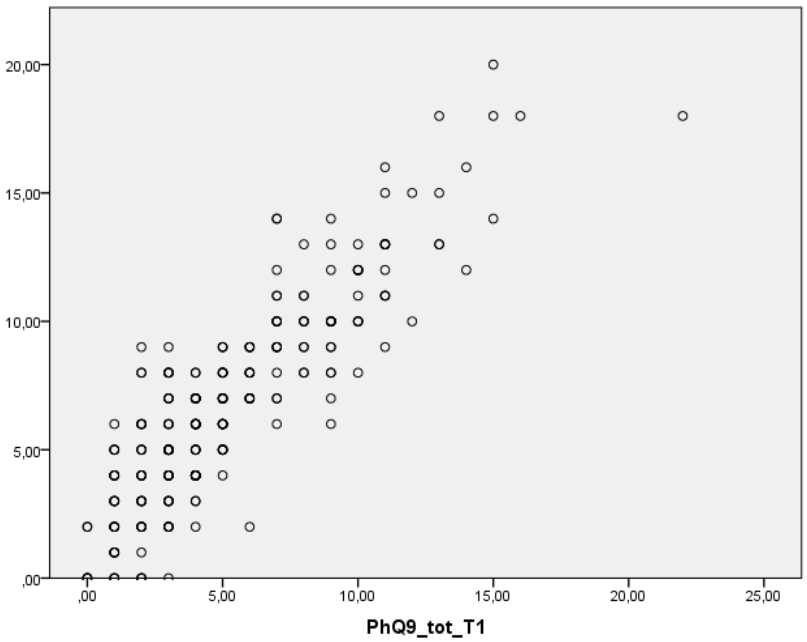

Grafico 19: EPDS e PHQ 9 a T1

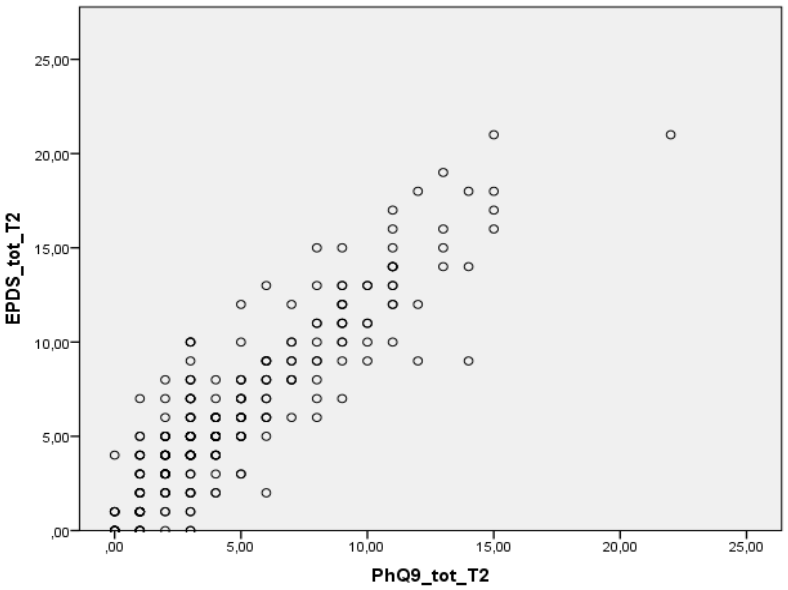

Grafico 20: EPDS e PHQ 9 a T2

I rispondenti sono stati coerenti ed i questionari risultano equivalenti.

j) Analisi fattoriale EPDS e PHQ 9

I fattori indipendenti posseduti dalla scala EPDS alla rotazione Varimax sono espressi in entrambi i gruppi nella Tabella 19.

Tabella 19: Analisi fattoriale EPDS nei due gruppi

EPDS - Gruppo A	F1	F2	F3
T0	5,4,6,3	9,8,2,1	10,7
T1	3,5,4,6	9,8,	1,2
T2	5,6,4,3	9,8,7	1,2
EPDS - Gruppo B	F1	F2	F3
T0	7,9,8,4	6,3,5	2,1,10
T1	9,8,6,7	4,5,3	1,2,10
T2	8,9,10,7	4,5,6,3	2,1

I fattori indipendenti posseduti dalla scala PHQ 9 alla rotazione Varimax sono espressi in entrambi i gruppi nella Tabella 20.

Tabella 20: Analisi fattoriale PHQ 9

PHQ 9 - Gruppo A	F1	F2	F3	F4
T0	2,9,7,1,	5,6,4	3,8	
T1	3,4,7,1,8,	9,2,	6,5	
T2	7,3 4,1,8,	2,5,9,	6	
PHQ 9 - Gruppo B	F1	F2	F3	F4
T0	3,7,	6,2,9	5,8,4,1,	
T1	2,1,6,	3,4,7,	5,8	9
T2	3,4,7,	2,6,1,	5,8,9	

IX. Risultati Estratti Dalle Cartelle Cliniche Della Gravidanza

Confronto delle analisi chimico cliniche fra il Gruppo A e il Gruppo B durante la gravidanza

Per ciò che concerne le analisi effettuate durante la gravidanza, il confronto fra il Gruppo A e il Gruppo B di controllo è stato condotto utilizzando il test non parametrico U di Mann-Whitney a campioni indipendenti e ad un livello di significatività $<0,05$.

Si sono rilevate differenze tra i due gruppi nelle seguenti variabili:

- distribuzione della media del peso acquisito durante la gravidanza fra la 15-26^{W} ($p=0,20$); fra la 27-41^{W} ($p=0,25$).
- distribuzione della pressione minima a 32^{W} ($p=0,19$); 39^{W} ($p=0,19$)
- distribuzione della albumina a 28^{W} ($p=0,033$), a 31^{W} ($p=0,030$)
- distribuzione della glicemia a 24^{W} ($p=0,03$); 28^{W} ($p=0,02$); 36^{W} ($p=0,043$) distribuzione dell'acido urico a 35^{W} ($p=0,030$)
- distribuzione delle piastrine a 29^{W} (0,040).

Grafici da 21 a 26

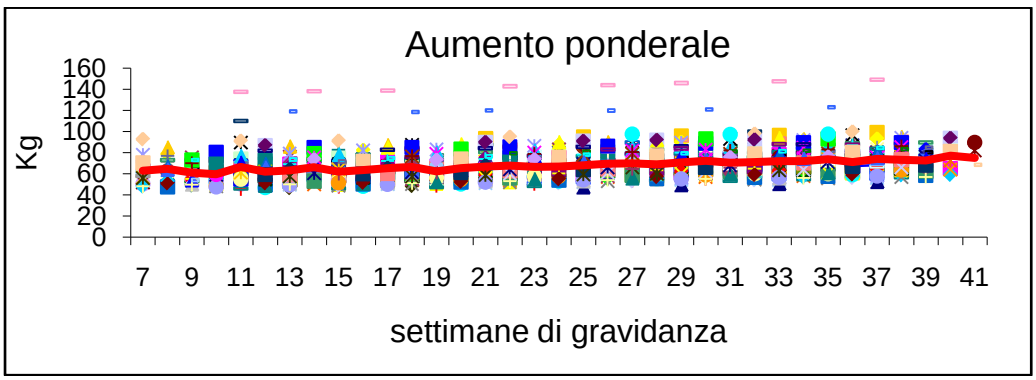

Grafico 21: Andamento peso materno durante la gravidanza

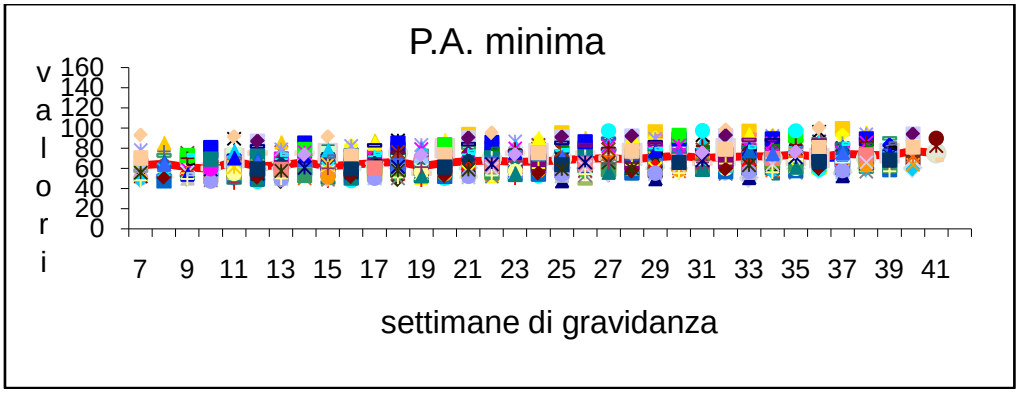

Grafico 22: Pressione arteriosa minima

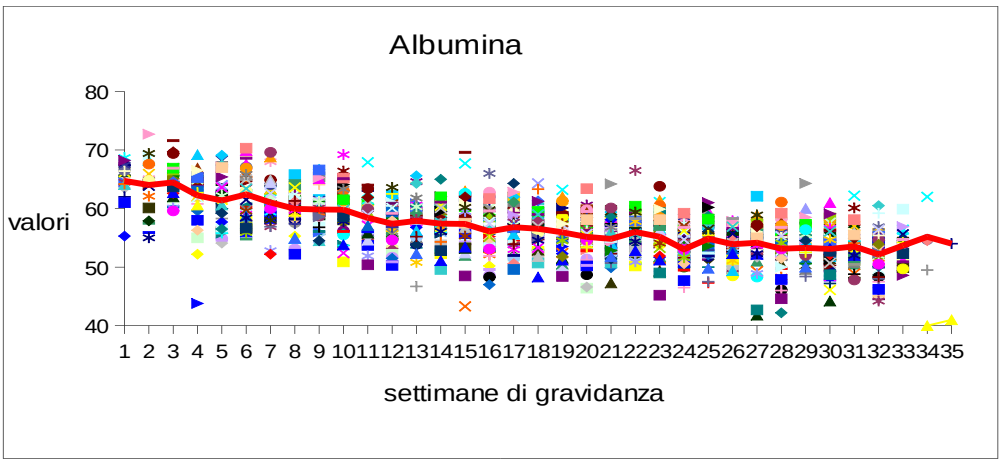

Grafico 23: Albumina

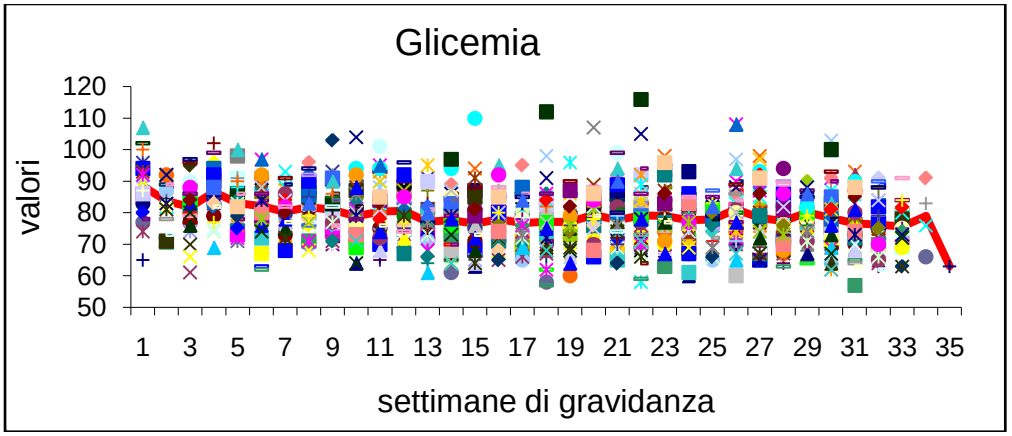

Grafico 24: Glicemia

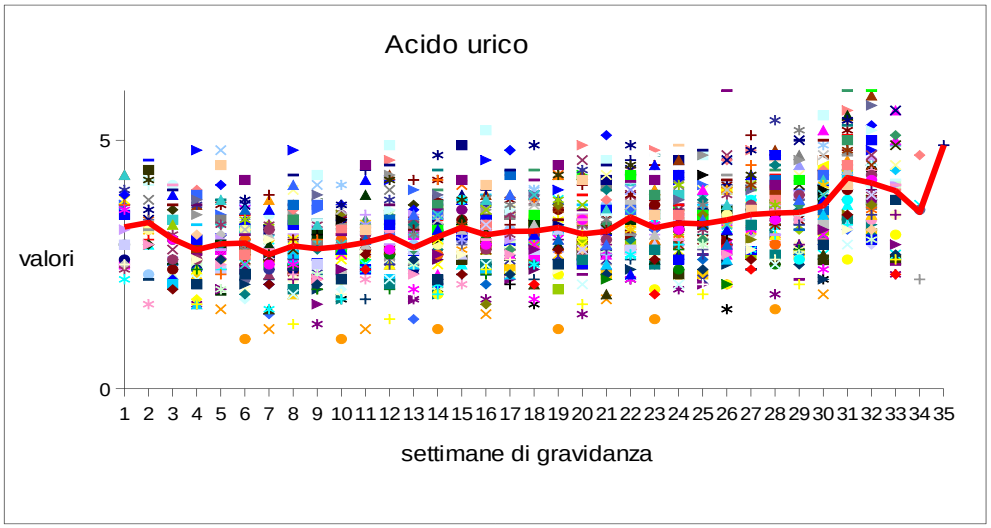

Grafico 25: Acido urico

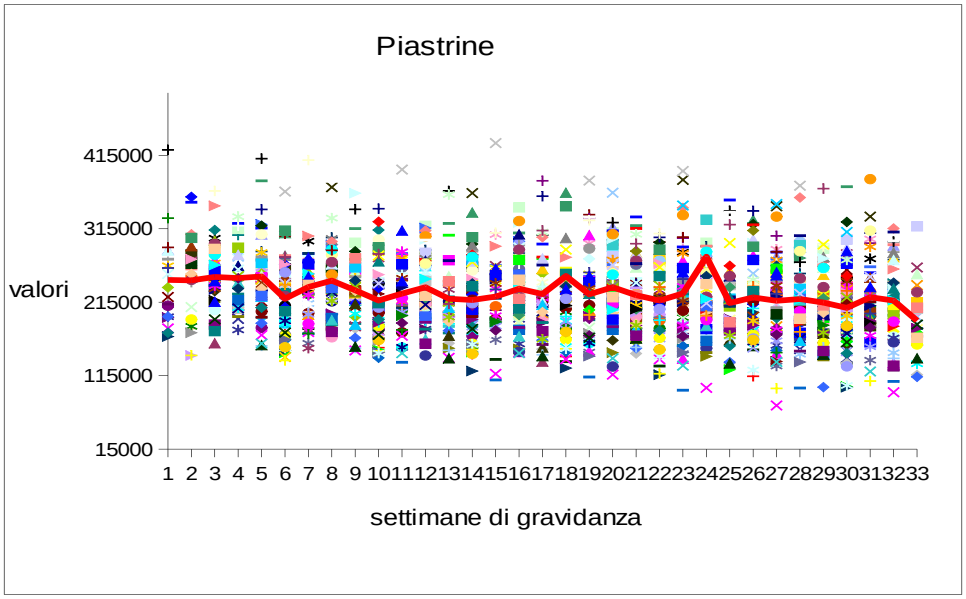

Grafico 26: Piastrine

X. Maternity Blues

a) Introduzione

Durante la gravidanza e dopo il parto si verificano nella donna degli importanti cambiamenti emotivi. Il Maternity Blues (MB) è un cambiamento di umore transitorio che si verifica soprattutto tra il 1° e il 10° giorno di post-partum.

E' caratterizzato da tristezza, pianto improvviso, lieve stato d'ansia, paura.

Tali sintomi tendono a scomparire rapidamente, ma se permangono o peggiorano vengono inquadrati come depressione post-partum.

Diversi studi riportano la frequenza del MB compresa nel campo 4-80%.

Per determinare una eventuale loro correlazione con il MB, vengono studiati sia parametri biologici che psicosociali. Secondo la maggior parte degli autori, le informazioni su MB, maternità e supporto alla donna sono il modo migliore per affrontare il MB sia in via preventiva che terapeutica (Beck CT et al., 1992; Gonidakis, 2007).

Uno studio di Boudou et al. (2007) identifica un'associazione tra l'intensità del dolore della nascita e l'intensità del MB considerandolo come forte predittore di depressione post-natale; questo dato è confermato anche in altre popolazioni, donne giapponesi incluse (Watanabe et al., 2008).

In Italia, Grussu e Quatraro (2013) in uno studio condotto tra il 1° e il 5° giorno dopo il parto su 36 primipare, hanno studiato sia i sintomi psicologici che i disturbi dell'umore di lieve entità; i sintomi somatici erano particolarmente acuti nei primi giorni dopo il parto.

b) Descrizione dell'indagine pilota

Al fine di conoscere il valore del Maternity blues, in un campione casuale, costituito dal 10% del totale delle donne (251), è stata effettuata un'indagine pilota con le stesse modalità e gli stessi strumenti della ricerca primaria.

Previo consenso informato, sono stati somministrati, a 3-4 giorni dal parto, i test EPDS, PHQ 9 e SF 36 ed è stata effettuata un'intervista strutturata tesa a far emergere i fattori di rischio socio-demografici/culturali/ambientali, psicologici e clinici già individuati dalla letteratura (Beck, 2001; Monti et al., 2006).

c) Descrizione dei risultati

EPDS: sono risultate positive n°10♀ - 40% (cut-off ≥9)

PHQ 9: sono risultate positive, n°5♀ -20% (cut-off ≥9)

E' stato effettuato il test non parametrico U di Mann-Whitney a campioni indipendenti per verificare la differenza tra le due categorie (EPDS positivi/EPDS negativi) rispetto alle principali variabili rilevate tramite l'intervista.

Ad un livello di significatività di $<0,05$ si sono rilevate differenze tra le due categorie nelle seguenti variabili: a) settimana di gravidanza e b) episodi importanti (*'life stress events'*) risultati in accordo con la letteratura scientifica.

d) Risultati SF36

La media dei risultati dei domini e degli indici sintetici dell'SF 36 (versione acuta) a 3-4 giorni dal parto è inserita nella Tabella 21 e nei Grafici 32-34.

Tabella 21: Risultati domini SF 36

	Media	Dev.std.	Media	Dev.std.	Media	Dev.std.
Attività fisica	81,43	18,19	86,25	11,10	86,67	10,33
Ruolo e salute fisica	42,86	47,25	43,75	40,06	62,50	41,08
Dolore fisico	75,71	13,19	70,17	24,64	50,33	18,05
Salute in generale	62,14	10,90	67,17	13,60	71,33	14,60
Vitalità	45,71	10,18	57,92	13,56	53,33	12,11
Attività sociali	39,29	15,19	43,75	19,58	33,33	15,14
Ruolo e stato emotivo	42,86	37,09	61,11	27,83	27,78	38,97
Salute mentale	59,43	13,55	65,00	19,00	58,67	18,36
PCS	48,29	5,57	47,56	6,84	50,11	5,36
MCS	35,52	8,27	41,00	9,48	33,21	9,16

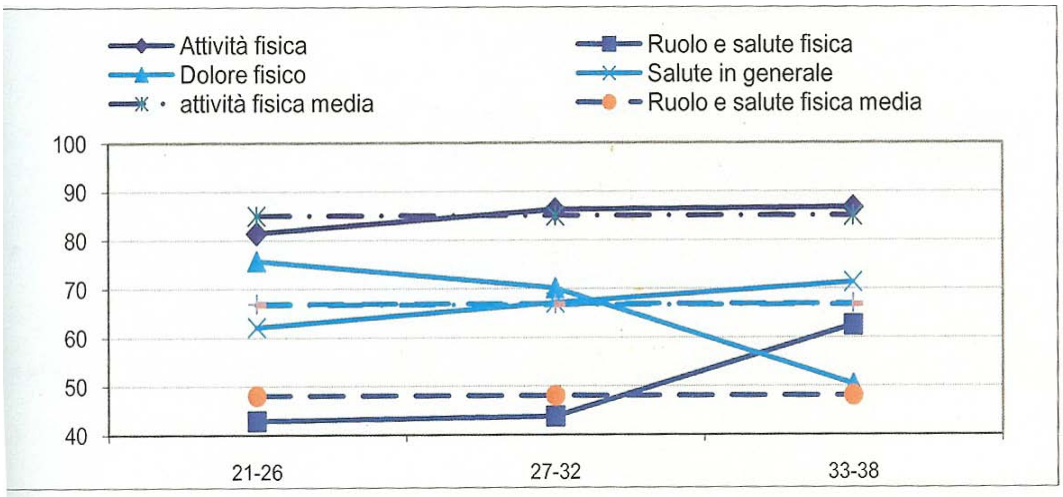

Grafico 26: Risultati domini fisici SF 36 per classi d'età

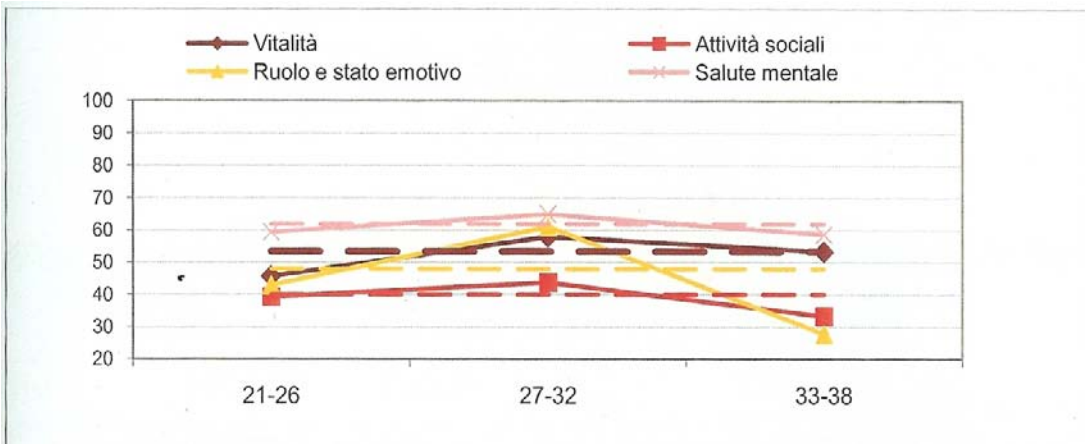

Grafico 27: Risultati domini mentali SF 36 per classi d'età

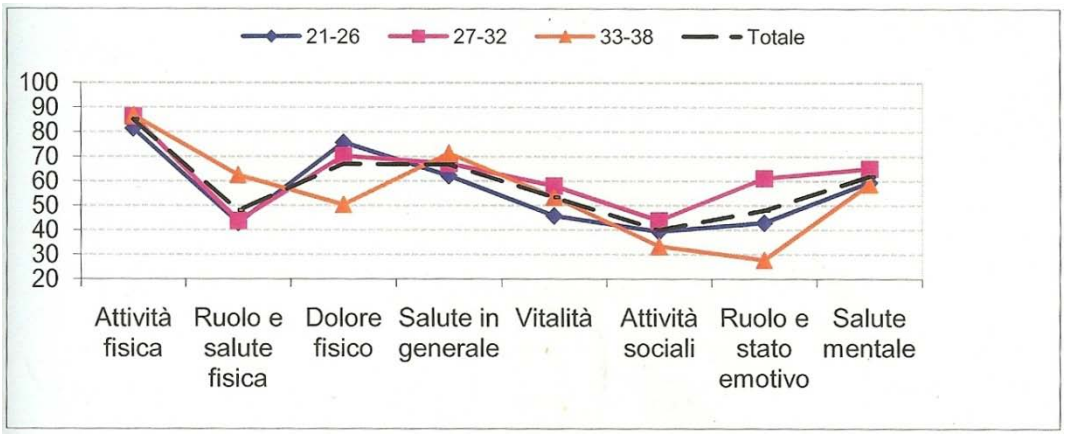

Grafico 28: Risultati domini totali SF 36

e) Analisi fattoriale

I fattori indipendenti posseduti dalla scala stessa alla rotazione Varimax sono inseriti nella Tabella 21 (EPDS) e nella Tabella 23 (PHQ 9).

Tabella 22: Fattori EPDS

		FATTORE1	FATTORE2	FATTORE3
EPDS	NEGATIVI	4,1,2,7,10	3,9	8, 6, 5
	POSITIVI	2,1,5,8,10	7,6,3	4,9

Tabella 23: Fattori PHQ 9

		FATTORE1	FATTORE2	FATTORE3
PHQ 9	NEGATIVI	5,6,2,8	3,7	1,4
	POSITIVI	4,3	5,2,6	1,8,7

XI. Discussione

I risultati ottenuti dalla ricerca nel campione totale di donne (251), mostrano che l'età media delle gravide è pari a 32,5 anni (21-42), quella paterna pari a 36 anni (22-60).

Il livello di scolarità del campione è medio-alto, 77% nelle donne e 73% nei mariti/compagni; la disoccupazione è maggiore fra le donne rispetto agli uomini (13% *vs* 5%) con una precarietà delle lavoratrici del 43%; le posizioni professionali gerarchicamente più elevate ricorrono nelle donne con frequenza dimezzata rispetto agli uomini (8% *vs* 16%).

Le coppie, hanno dichiarato una stabilità economica pari all'86% (con ciò suggerendo un target di popolazione di fascia media) ed una stabilità affettiva del 94%.

Il campione, costituito prevalentemente da donne in attesa del primo figlio (66,5%) ha scelto un'assistenza alla gravidanza di tipo privato (98%).

Le gravidanze sono risultate, per il loro decorso, per lo più a basso rischio (94%).

Il ricorso ad indagini strumentali ecografiche è stato per il 69% coerente con le raccomandazioni delle linee guida; le donne hanno avuto un aumento ponderale medio di 11,2 Kg. (4-22Kg); ha praticato attività sportiva il 21% di esse, mentre il 7,2% lo ha sospeso.

Delle pluripare (33,5% del campione), solo il 20% aveva seguito un corso di accompagnamento alla nascita alla prima gravidanza.

Il 45% del campione totale di gravide ha accettato di entrare nel gruppo di intervento tra la 22^{a} e la 24^{a} settimana di gravidanza; durante tutto l'intervento non si sono verificati abbandoni.

a) Discussione SF 36

Dall'analisi degli otto domini e dei due indici sintetici dell'SF 36 effettuata sul campione totale di 251 donne, emergono i dati che descrivono il benessere materno nella *sfera fisica* (PCS) attestandolo ad una media di 50,5 (su 100) in gravidanza (T0), a 45,5 ad un mese dal parto (T1) e a 53,6 a tre mesi dal parto (T2); si tratta di valori globalmente soddisfacenti, che comprensibilmente diminuiscono a T1 dopo l'evento parto, e che tornano ad aumentare a T2.

Nella *sfera mentale* (MCS) i valori risultano 51 a T0, 50 a T1 e 36,5 a T2. Si evidenzia il valore più basso a T2.

Le medie dei singoli domini e degli indici sintetici messi in relazione nei tre tempi alle quattro classi di età (anni 21-26; 27-32; 33-38; 39-42) indicano che:

A T0 - nel dominio dell'*attività fisica*, (range 86 e 91) e del *ruolo e salute fisica* (59-67) i valori alti sono delle donne più giovani (21-26 anni); il *dolore fisico* (85-91) più basso, indice di un benessere maggiore, e la *salute in generale* (67-72) più alta è fra le donne 33-38enni.

L'indice sintetico PCS, in tutte le categorie di età, risulta superiore a 50 con minime variazioni, (50-51).

Nei domini mentali: la *vitalità* (79,5-82,5) è più alta fra le 27-32enni, le *attività sociali* (76-81) e il *ruolo e stato emotivo* (58-67) nelle più giovani e la *salute mentale* (78-84) nelle 27-32enni.

L'indice sintetico MCS è superiore a 50 nelle donne le cui età sono comprese nel range 21-26, 27-32 e 33-38, mentre scende al di sotto di 50 (48,5-51,6) nella fascia d'età più adulta (39-42 anni).

A T1 - nel dominio dell'*attività fisica* (81- 89) i valori alti sono nelle più giovani, nel *ruolo e salute fisica* (36,6-45) fra le 27-32enni; nella *salute in generale* (60-66,7) i valori più alti sono nelle due categorie delle donne più giovani, nel *dolore fisico* (68-74) i valori più bassi, quindi indice di un benessere maggiore, sono fra le 33-38enni.

L'indice sintetico PCS, si attesta sotto a 50 in tutte le categorie d'età (45-46,3).

Nei *domini mentali*: la *vitalità* (65,8-69,6) è più alta nelle 27-32enni, le *attività sociali* (74,5-81,7), il *ruolo e stato emotivo* (56-63,8) sono più alti fra le più giovani e la *salute mentale* (72-80,3) è migliore fra le due categorie più giovani.

L'indice sintetico MCS è superiore a 50 nelle donne comprese nelle due categorie più giovani (21-26 e 27-32) mentre scende al di sotto di 50 nelle ultime due fasce d'età (33-38 e 39-42).

A T2 - nel dominio dell'*attività fisica* (88- 93,5) e *ruolo e salute fisica* (63-68,7) i valori alti sono nelle più giovani, nel *dolore fisico* (75-78,5) i valori più bassi, e quindi un benessere maggiore, permane in tutti e tre i tempi (T0, T1, T2) fra le 33-38enni, mentre, per la *salute in generale* (60-66,7) i valori più alti si riscontrano fra le 27-32enni.

L'indice sintetico PCS, si attesta sopra a 50 in tutte le categorie d'età (53,3-54,5).

Nei *domini mentali*: la *vitalità* (29,4-34,2) è più alta nelle più adulte; nelle *attività sociali* (70-80,8) e nel *ruolo e stato emotivo* (40-58,8) i punteggi maggiori si hanno tra le 27-32enni, e la *salute mentale* (53-56,4) è migliore fra le due categorie più adulte.

L'indice sintetico MCS è globalmente basso, inferiore a 50 (35-37,4); il valore migliore si riscontra tra le 27-32enni.

Questi risultati dimostrano come a T2 la globalità del campione dichiara una bassa vitalità e fornisce la percezione di un grado di stanchezza e di energia molto elevato esteso per lo più a tutte le classi d'età; questo aspetto non può non essere considerato nell'analisi del relativo indice sintetico mentale, anch'esso globalmente basso.

Attraverso l'utilizzo del test non parametrico U di Mann-Whitney a campioni indipendenti e ad un livello di significatività $<0,05$ si è effettuato il confronto dell'SF 36 fra il Gruppo A e il Gruppo B a T0, T1 e T2.

A T0 risulta significativa l'*attività fisica* ($p=0,007$).

A T1 risulta significativo ($p=0,013$) il *dominio sintetico fisico PCS*, insieme alla *salute in generale* ($p=0,000$), alla *vitalità* ($p=0,004$), alla *salute mentale* ($p=0,004$) e al *dolore fisico* ($p=0,036$).

A T2 nei domini fisici, le differenze fra i due gruppi erano presenti nelle seguenti variabili: *ruolo e salute fisica* ($p=0,003$) e *salute in generale* ($p=0,000$).

b) Discussione risultati EPDS

Come suggerito dalla letteratura scientifica in questo studio è stato utilizzato come 'cutpoint' positivo un EPDS ≥ 13, capace cioè di identificare le donne a rischio per la depressione post-partum.

Utilizzando il test non parametrico per campione singolo (Kolmogorov-Smirnov), i risultati positivi EPDS del campione globale (251 ♀), sono a T0 al 7%, a T1 al 9% e a T2 al 12%.

Gli EPDS positivi a T0 sono stati nel Gruppo A del 6% *vs* 8% del Gruppo B; a T1 le percentuali sono risultate uguali al 9%, in entrambi i gruppi; mentre a T2 essere inclusi nel Gruppo A d'intervento incide positivamente con il 4% *vs* 18%.

Nel Gruppo A, inoltre, sono state effettuate le correlazioni fra le variabili socio-demografiche e cliniche e l'EPDS, pertanto risultano significative a livello 0,01 le seguenti correlazioni:

- *Life stress events* a T1
- Avere familiari depressi a T1 e T2
- Avere familiari depressi in terapia a T1 e T2
- Tipo di allattamento a T1

Con una significatività a 0,05:
Il praticare sport, a T0

- Life events a T0
- La condizione professionale materna a T1 e T2
- Avere familiari depressi in terapia a T0
- Tipo di allattamento a T2

c) Discussione risultati PHQ 9

I dati ottenuti dallo studio dell'EPDS sono confermati da un andamento coerente ottenuto anche dai test PHQ 9.

Riguardo al test PHQ 9, ad un 'cutpoint' positivo ≥11, nel campione globale (251 ♀), le percentuali sono state le seguenti: a T0 il 6%, a T1 il 10% e a T2 l'11%.

I PHQ 9 positivi a T0 sono stati nel Gruppo A il 5,4% *vs* 6,4% del Gruppo B; a T1 le percentuali sono risultate dell'8,1 vs 10,7%; mentre a T2 essere inclusi nel Gruppo A d'intervento incide positivamente con il 3,6% *vs* 16,4%.

I risultati indicano che, nelle donne che hanno partecipato all'intervento, c'è stata una diminuzione significativa nei punteggi relativi alla Edinburgh Postnatal Depression Scale e al Patient Health Questionnaire 9, a 3 mesi dal parto.

Infatti entrambi i gruppi sono partiti da un livello di benessere materno in gravidanza pressoché uguale; ad un mese dal parto, come era comprensibile è diminuito, ma a 3 mesi, l'aver continuato il training anche in puerperio, può spiegare come il Gruppo A abbia goduto di un evidente maggior benessere rispetto al gruppo B il quale, invece, ha visto a tre mesi dal parto un significativo incremento del disagio riferito a depressione post natale.

In questo studio, i dati ottenuti dallo studio dell'EPDS e del PHQ 9 mostrano un andamento coerente rilevato in entrambi i test, i quali indicano un'aderenza ed una partecipazione leale dei soggetti, con risposte non espresse a caso da parte delle donne.

d) Discussione risultati test di concordanza EPDS e PHQ 9

Come obiettivo secondario, la presente ricerca si proponeva di eseguire la comparazione dei test EPDS e PHQ 9, nonché di effettuare l'analisi fattoriale dei due test nel campione totale a T0, T1 e T2.

In base ai riferimenti tratti dallo studio di Yawn et al. (2009) negli USA, effettuato solo nel post-partum, con il test non parametrico U di Mann-Whitney a campioni indipendenti, anche nel presente studio risultano significativi ad un livello di 0,05 l'EPDS a T2 e il PHQ 9 a T2, confermandone la concordanza.

Inoltre, in questa tesi si sono rilevate le correlazioni tra i questionari EPDS e quelli PHQ 9 non solo ad un mese dal parto (T1) ma anche in gravidanza (T0), e a tre mesi dal parto (T2), trovando in tutti e tre i tempi di follow-up una significatività pari a 0,01.

Se ne deduce che anche nella popolazione italiana, tra i questionari EPDS e quelli PHQ 9, i rispondenti sono stati coerenti e che i questionari risultano pertanto equivalenti.

e) Discussione Analisi fattoriale EPDS

La struttura multifattoriale della scala EPDS è già stata suggerita da diversi studi condotti in Francia, Australia ed Inghilterra (Adouard, 2005; Chabrol, 2004; Matthey, 2008); parecchi autori hanno trovato una struttura a due ma anche a tre fattori con la comparsa frequente di una dimensione secondaria costituita da una sintomatologia ansiosa (Brouwers, 2001; Jomeen, 2005; Ross, 2003; Thuoy, 2008). Peraltro, va detto che l'esatta identificazione dei fattori è diversa all'interno dei singoli studi. Tali differenze potrebbero essere dovute alle differenti popolazioni studiate, e alle diverse metodologie statistiche utilizzate.

L'unico studio italiano reperito (Petrozzi e Gagliardi, 2013) ha utilizzato per l'analisi fattoriale la rotazione obliqua ed ha identificato tre fattori:

Fattore 1 - la depressione (item 7,8,9,10);

Fattore 2- l'ansia (item 3,4,5,6),

e infine Fattore 3- l'anedonia (item 1,2),

con un risultato sostanzialmente in accordo con lo studio di Thuoy e McVey, (2008) effettuato però con un procedimento statistico diverso e su una popolazione diversa.

Nella seguente Tabella 24. sono elencati gli studi e gli item relativi ai fattori quanto statisticamente significativi.

Tabella 24: Studi fattoriali EPDS

STUDI	F1	F2	F3
1. Adouard et al., 2005	1,2,7,8,9	3,4,5,6,10	
2. Matthey, 2008	1,2,6,7,8,9,10	3,4,5	
3. Lloyd-Williams et al., 2000	6,8,9,10	3,4, 6,7	
4. Brouwers et al., 2001	1, 2, 8, 9	3, 4, 5	10
5. Ross et al., 2003	1, 2, 8, 9	3, 4, 5	10
6. Chabrol & Teissendre, 2004	8, 9, 10	3, 4, 5, 6, 7	1, 2
7. Jomeen & Martin, 2005	1, 2, 6, 7, 8, 9	3, 4, 5	10
8. Montazeri et al., 2007	6, 7, 8, 9, 10	3, 4, 5	1, 2
9. Tuohy & McVey, 2008	7, 8, 9, 10	3, 4, 5	1, 2
10. Petrozzi & Gagliardi, 2013	7, 8, 9,10	3, 4, 5, 6	1, 2
11. Gruppo A del presente studio a T2	5,6,4,3	9,8,7	1,2
12. Gruppo B del presente studio a T2	8,9,10,7	4,5,6,3	2,1

Gli item 1-2, sono stati aggregati spesso con la componente depressiva per la loro similarità sintomatologica, piuttosto che con la sintomatologia ansiosa, ma metodi analitici più raffinati permettono di distinguere l'anedonia dalla depressione e aggregano tali item come a sé stanti nel Fattore 3.

Tale aggregazione è rilevabile anche nel presente studio, nel Gruppo B in tutti e tre i tempi e nel Gruppo A a T1 e T2.

Gli item 3-5, in molti studi, sono stati trovati maggiormente aggregati al fattore 'ansia' e l'item 6 variabilmente associato agli item 3-5; dato analogo è stato rilevato anche nel presente studio in entrambi i gruppi.

Nella presente ricerca l'associazione quantitativa (loading) degli item nel Gruppo B risulta in linea con la letteratura internazionale e con il lavoro italiano precedentemente citato.

Nel Gruppo A il Fattore 1 risulta essere costituito a T0 e mantenuto a T1 e T2 dalla componente ansiosa, il Fattore 2 dalla componente depressiva e il Fattore 3 dall'anedonia (a T1 e T2).

Risultato che potrebbe spiegare come mai a T2 il Gruppo A ottiene un 'outcome' maggiormente positivo rispetto a quello del Gruppo B.

L'item 10 nel Gruppo A si colloca nel Fattore 3 e si associa con l'item 7, ma a T1 e T2 non si associa a nessuno dei tre fattori.

f) Discussione Analisi fattoriale PHQ 9

La struttura multifattoriale del test PHQ 9, è stata studiata sopratutto nell'ambito delle cure primarie, in diversi gruppi etnici ed in relazione a molti altri test utilizzati nella rilevazione della depressione (BDI, SCID, ecc.).

Le aree studiate sono molto diverse e vanno dalle lesioni del midollo spinale alle cure palliative, al confronto fra i due sessi, negli studenti universitari latini e non latini, afro-americani, e negli adolescenti cinesi.

Da un modello unifattoriale trovato da Bombardier et al. (2004) e successivamente riconfermato da Huang et al. (2006), diversi studi hanno evidenziato una struttura a doppio fattore (Richardson e Scott, 2008; Dum et al., 2008; Granillo, 2012; Chilcot et al., 2013; Tsai et al., 2014) rappresentati da elementi affettivi/cognitivi ed elementi somatici.

In un recente studio effettuato su un campione di 2615 soldati della Guardia Nazionale dell'Ohio, Elhai et al., (2012) hanno esaminato la struttura fattoriale dei principali sintomi della depressione maggiore confrontando quattro modelli utilizzati in letteratura per l'analisi fattoriale del PHQ 9 (Tabella 25).

Essi hanno affermato che i sintomi di depressione maggiore sono meglio rappresentati distinguendo i Fattori Somatici (S) da quelli Non-somatici (N-S), piuttosto che da un Fattore Unidimensionale, Depression (D).

Distinzione questa, che non risulterebbe essere solo interna allo strumento (PHQ 9), ma probabilmente rappresenterebbe rapporti differenziali con altri tipi di psicopatologia.

Fra i modelli presi in esame, da criteri statistici oggettivi relativi al campione in oggetto, il migliore risulterebbe essere il Modello 2b. Esso concettualizza l'item 1 'Anhedonia' come parte del Fattore Non-somatico e l'item 7 'Concentration difficulties' come parte del Fattore Somatico.

Tabella 25: Studi fattoriali PHQ 9 adattata da Elhai et al., 2012.

PHQ 9 items				
N.B. I modelli sono stati empiricamente testati in base al DSM-IV.	1	2a Krause et al., 2008 e 2010	2b Krause et al., 2008 Richardson e Richards, 2008	2c Krause et al., 2010
1. Anhedonia	D	N-S	N-S	N-S
2. Depressed mood	D	N-S	N-S	N-S
3. Sleep difficulties	D	S	S	S
4. Fatigue	D	S	S	S
5. Apetite change	D	S	S	S
6. Feeling of worth lessness	D	N-S	N-S	N-S
7. Concentration	D	N-S	S	S
8. Psichomotor agitation	D	N-S	S	S
9. Thoughts of death	D	N-S	N-S	N-S

L'analisi fattoriale eseguita in questo studio attraverso la rotazione Varimax, mostra la presenza nel Gruppo A di ben tre Fattori con la presenza di elementi Non-somatici variamente associati con elementi Somatici; solo a T2, il Fattore 3, si delinea singolarmente nell'item 6 (Tabella 26.)

Tabella 26: Analisi fattoriale PHQ 9

		Fattore1	Fattore 2	Fattore 3
Gruppo A	T0	2,9,7,1	5,6,4	3,8
	T1	3,4,7,1,8	9,2	6,5
	T2	7,3, 4,1,8	2,5,9	6

Questi risultati, non essendo un obiettivo primario della presente ricerca, sono stati esclusivamente osservati, pertanto per essere correttamente interpretati necessitano di maggiore approfondimento ed aprono nuovi ambiti di ricerca.

XII. Conclusioni

Dallo studio effettuato è emerso che il training perinatale effettuato sul Gruppo A costituito da 111 donne e comparato con un Gruppo B (di controllo) di 140 donne, è risultato gradito dalle donne, tanto che l'indice di abbandono del training è stato pari a zero.

Questo dato sottolinea ed è concorde con lo studio di Hollins et al., 2013, che afferma che se le donne percepiscono il valore della formazione come fondamentale per il risultato della propria esperienza non mostrano barriere o resistenze e partecipano attivamente.

I risultati indicano che l'aver partecipato all'intervento ha influito positivamente sullo stato di benessere materno evidenziando una diminuzione significativa nei punteggi EPDS e PHQ 9 a 3 mesi dal parto (T2).

L'intervento ha prodotto un risultato statisticamente e significativamente positivo in più aree. Dall'analisi condotta sui dati estratti dalle cartelle cliniche della gravidanza, l'aver effettuato attività fisica controllata durante la gravidanza non è stato solo un importante mediatore nel veicolare interventi di tipo psicologico sulle donne, e quindi aver influito positivamente sulla sintomatologia depressiva, ma ha anche sortito un effetto positivo sul benessere fisico materno.

L'attività fisica, infatti, ha concorso a mantenere lo stato di benessere delle donne durante la gravidanza attraverso un aumento ponderale materno più contenuto e livelli glicemici e di pressione minima più bassi. Aumento ponderale ridotto e bassi livelli glicemici risultati da questa ricerca sono stati rilevati anche da Horan et al., (2013).

L'importanza dell'attività fisica e la sua associazione inversa con sintomi depressivi in gravidanza (Meltzer et al., 2010;) e nel periodo post-natale, sono stati confermati successivamente alla ricerca da importanti studi a livello internazionale (Loprinzi et al., 2012; Evenson et al., 2012; Teychenne e York, 2013; Claesson et al., 2013, Mc Arthur et al., 2013) suggerendo agli operatori della nascita di contribuire a facilitare l'attività fisica nel periodo perinatale.

I risultati di questo studio mostrano che la salute relativa alla qualità e allo stile di vita a partire dalla gravidanza e nel periodo postnatale merita ulteriore attenzione.

Associare alle visite prenatali incontri settimanali di training nei quali praticare attività fisica e consigliarne un programma da eseguire durante la settimana, sarebbe in grado di migliorare lo stato funzionale della sfera fisica durante la gravidanza e potrebbe influenzare

la percezione della qualità della vita per tutto il corso della gravidanza e nel puerperio.

Il sostegno telefonico nell'immediato post-partum con il ricercatore/caregiver e gli incontri protratti fino al 3° mese di puerperio, hanno probabilmente influenzato il 'processo di *empowerment'* delle donne che si è concretizzato in un processo di "restituzione" attraverso il miglioramento del proprio stato emotivo e la netta diminuzione dei livelli depressivi a tre mesi (T2).

Un'altra ipotesi per questo risultato positivo a T2 potrebbe essere dovuto all'interazione costante con il neonato durante il training quale mitigatore della disregolazione emotiva dovuta all'ansia come suggerito da Lonstein, 2007 e al sostegno attuatosi nel gruppo, fra pari come rilevato da Dale et al., in una review Cochrane del 2008.

Come confermato anche da Jokhi R., 2013, per gli operatori sanitari che si occupano dei servizi di benessere materno infantile ed in particolare per le ostetriche/ci, è auspicabile prevedere una formazione specifica al fine di implementare le conoscenze e metterli in grado di poter rilevare l'eventuale presenza di sintomi depressivi e di contribuire a promuovere la sanità mentale nel periodo perinatale.

In linea con i dati provenienti da studi sperimentali e le conseguenti indicazioni delle linee guida NICE, questo studio ha valutato il benessere materno dalla gravidanza ai tre mesi dopo il parto sia nei due gruppi che nel campione totale di 251 donne.

Il test SF 36, che misura la qualità di vita, ed è comunemente utilizzato nella letteratura scientifica internazionale come misura di esito, ha descritto sia i domini fisici che mentali in associazione con i test EPDS e PHQ 9.

Globalmente l'SF 36 mostra che il benessere maggiore in gravidanza nella sfera fisica è a vantaggio di un benessere materno migliore nel Gruppo A.

Nel campione totale il valore basso della '*sfera mentale'* (MCS) a T2, indica un momento di vulnerabilità della sfera mentale della donna e suggerisce l'importanza di una valutazione in tale epoca dello stato di benessere materno.

Questi risultati dimostrano come a T2 la globalità del campione dichiara una bassa vitalità e fornisce la percezione di un grado di stanchezza e di energia molto elevato ed esteso per lo più a tutte le classi d'età, e di questo va tenuto debito conto nell'analisi del relativo indice sintetico mentale, anch'esso globalmente basso.

Questo studio ha aggiunto, inoltre, una comparazione fra i due test di screening, dimostrandone la piena concordanza, aspetto questo che al momento non risulta essere stato studiato nella popolazione italiana ma solo in quella americana.

I fattori dell'EPDS analizzati rilevano le componenti relative agli stati ansiosi con risultati vicini allo studio italiano di Gagliardi e Petrozzi (2013) e viene dimostrata l' efficacia dell'intervento multidisciplinare a tre mesi dal parto.

I risultati di questo studio suggeriscono l'efficacia del training nonché l'estensione di intervento integrato tra attività fisica, sostegno psicologico e interventi sulla genitorialità, anche nei primi tre mesi di puerperio.

E' tuttavia necessario condurre altri studi per verificare e puntualizzare meglio gli interventi, ma a livello territoriale sarebbe auspicabile effettuare almeno una volta a trimestre uno screening per la depressione nelle gravide (ACOG, 2010).

Ridisegnare un periodo ante- e post-natale basando gli interventi sui bisogni fisici e psicologici individuali delle donne attraverso un sostegno e un accompagnamento al mantenimento o al raggiungimento di un corretto stile di vita permetterà l'estensione e l'influenza di tali acquisizioni in ogni momento della vita non solo della donna ma di tutta la famiglia.

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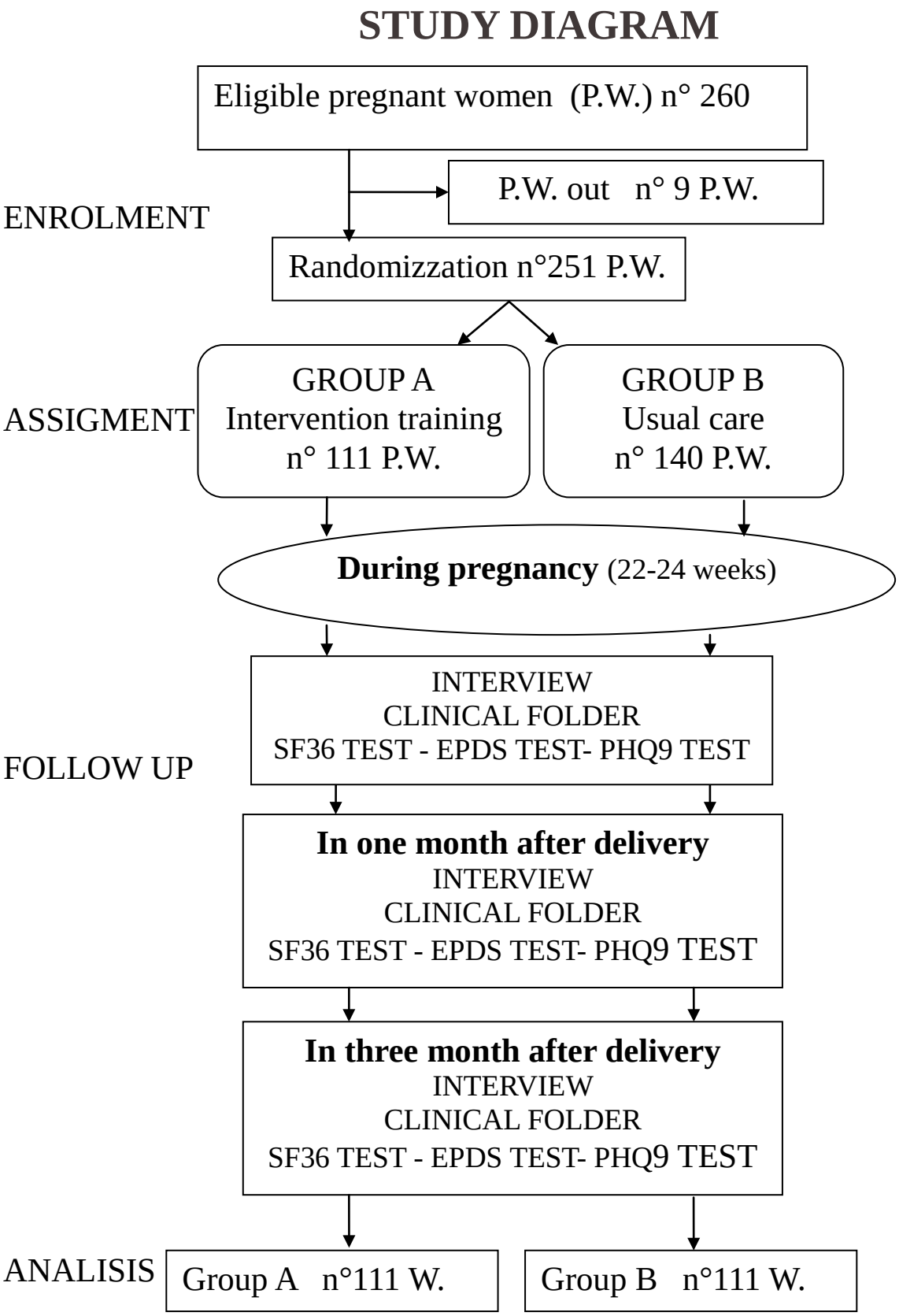
Allegato



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Covid and Pregnancy: The Possibility of Ambulatory Care

By Loutfi. Guennoun. A, Khouchoua. M, Rjafallah. A, Mesnane. S, Dr. Azzouzi Jaouad, Dr. Alaoui Omar, Sniter. KH & Lafkir. S

Abstract- In the current pandemic context linked to COVID 19, which has and which continues to mark our daily lives, we considered useful to share our data concerning pregnant women affected by this disease at the level of the province of Meknes (Morocco), which is a province of 835,695 inhabitants. Our experience concerns 11 patients confirmed positive for COVID, collected since the start of the pandemic in our country on 02/03/2020 to date on 01/10/2020 based on the data recorded in patient files archived at the level of the provincial reference center. This work traces the symptoms, diagnosis, treatment, management methods, and the evolution of the various parturients to date. The conclusion of this work remains comparable to the literature with one particularity: the care and the follow-up of 10 patients out of 11 (91%) was done with medical surveillance at home.

Keywords: *COVID 19, pregnancy, hydroxy-chloroquine, and ambulatory.*

GJMR-E Classification: *NLMC Code: WQ 240*

Strictly as per the compliance and regulations of:

Covid and Pregnancy: The Possibility of Ambulatory Care

Loutfi. Guennoun. A [α], Khouchoua. M [σ], Rjafallah. A [ρ], Mesnane. S [ω], Dr. Azzouzi Jaouad [¥], Dr. Alaoui Omar [§], Sniter. KH [χ] & Lafkir. S [ν]

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I. Introduction

The pregnant woman was always considered fragile and highly susceptible, given the physiological, hemodynamic, and anatomical changes induced by pregnancy. This fear is finding it's substantial legitimacy by considering the observation established according to the specialized literature: "The vulnerability of pregnant women to respiratory infections (such as influenza virus), as well as the increased complications observed during epidemics of various coronaviruses which preceded covid-19 (SARS-COV and MERS-COV) "(1). Without forgetting the immunological and physiological cardiopulmonary changes of pregnancy, which make pregnant women more vulnerable to infectious complications and respiratory pathologies. High rates of maternal complications (admission to intensive care, need for mechanical ventilation, and even death) as well as fetal complications (intrauterine growth retardation, premature births, or even fetal death in utero or even neonatal), were observed during previous SARS-COV and MERS-COV epidemics (2). However, to date, the majority of the available data related to infection with SARS-COV-2, also known as covid-19 in, pregnant women do not seem to indicate higher infection rates or increased risk of complications compared to the general population, except a few studies showing an increased risk of admission to intensive care (without increased risk of mortality) (3,4). But the current state of knowledge is well documented by a review of the literature made by Corinne Hubinont and her team (5), they made it clear that the majority of infected patients are not very symptomatic, 10% of them may present lung disease that is important to diagnose and treat. While specifying the existence of a significant risk of premature birth requiring the administration of antenatal corticosteroids for fetal lung maturation, but the infection does not affect the delivery route and does not contraindicate loco-regional anesthesia.

II. Means and Methods

The data was collected on the files of the various patients, the computer data recorded at the level of the computer database of the epidemiology service, the data collected by the medical follow-up at home, and the data of the social survey and the information. Provided by the application « wikaytna: our protection » downloadable on the phones of patients with Covid to determine contact subjects (Photo1).

Poto1: Illustration of the mobile application set up by the Moroccan health ministry for good traceability of affected subjects and contacts.

Author α: MD, Gynecology and obstetrics department, Sidi said hospital, Meknes, Morocco. e-mail: loutfimounaim@hotmail.com
Author σ § χ ν: MD, Medical administration and epidemiological services, Meknes, Morocco.
Author ρ ω: MD, Gynecology and obstetrics department, Pagnon hospital, Meknes, Morocco.
Author ¥: M.D pneumology department hospital center Med V, Méknès, Morocco.

III. Results

In our series, we have 11/1608 (0.7%) patients who were diagnosed affected by covid-19. Our screening strategy in the gyneco-obstetrics services was taken in consultation with all the stakeholders of the medical team, namely not to screen all the patients presenting to gyneco-obstetrics services, but rather those patients having clinical signs suggesting the Covid infection either because they were considered contact cases.

For more details, we preferred to put the results on descriptive tables given the small number of patients collected in our series:

Table 1: Summary of the age of the patients and their symptoms

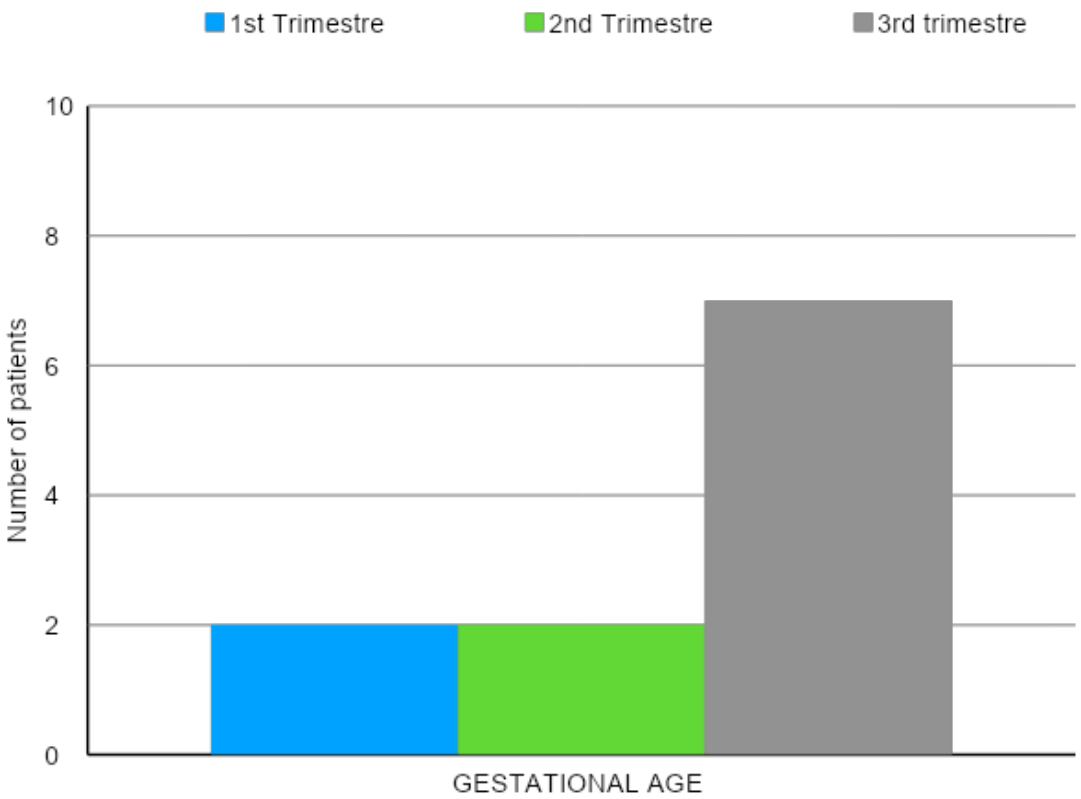
N° Patients	Age	Fever	Cough	Headache	Anosmia	Ageusia	Diarrhea	Dyspnea
1	28 Years	+	+	+	+	+	+	-
2	32 Years	+	+	-	+	+	-	-
3	31 Years	+	+	+	+	+	-	-
4	25 Years	-	-	-	-	-	-	-
5	37 Years	-	-	-	-	-	-	-
6	32 Years	+	+	+	+	+	-	-
7	33 Years	+	+	-	+	+	-	-
8	26 Years	+	+	+	+	+	-	-
9	36 Years	-	-	-	+	+	-	-
10	32 Years	+	+	+	-	-	-	-
11	37 Years	+	+	-	+	+	-	-

Table 2: Distribution of patients by trimester of onset of the disease

N° Patients	Vitamine C	Paracetamol	Zinc	Hydroxychloroquine	Azithromycin	Lopinavir	Healing	Progress of Pregnancy
1	+	+	+	+	+	+	+	Miscarriage 6 w 5 d
2	+	+	+	+	+	-	+	Normal childbirth at 38 w
3	+	+	+	+	+	-	+	Normal childbirth at 36 w
4	+	+	+	-	-	-	+	Caesarean 38 w
5	+	+	+	-	-	-	+	Ongoing pregnancy 35w
6	+	+	+	+	+	-	+	Ongoing pregnancy 33 w

7	+	+	+	+	+	-	+	Ongoing pregnancy 32 w
8	+	+	+	+	+	-	+	Ongoing pregnancy 31 w
9	+	+	+	+	+	-	+	Ongoing pregnancy 26 w
10	+	+	+	-	-	-	+	Ongoing pregnancy 19 w
11	+	+	+	+	+	-	+	Ongoing pregnancy 18 w

Table 3: Showing the different treatments taken by the patients and their evolution (W: Weeks, d: Days)



IV. Discussion of the Results

Since the diagnosis of the first case affected by covid-19 in our country and especially in our region in Meknes, the local scientific and epidemiological team have consulted on the care of pregnant women who would be proved affected by COVID 19 and the decision was: To hospitalize only pregnant patients with signs of severity or with comorbid factors as reported in the literature (Renal failure, heart failure, Insulin-dependent or complicated requiring diabetes (micro or macro angiopathy), chronic respiratory failure or asthma or cystic fibrosis or any chronic pathology that can decompensate during viral infection, immune depression (drug, uncontrolled HIV or CD4 <200 / mm), organ transplant, liver failure, hematologic malignancy, cancer, obesity (6,7 and 8) and we did not consider the 3rd trimester to be an aggravating factor, we have however established in addition to the surveillance Daily medical care at home by a general practitioner, follow-

up in obstetrical consultation every three days at a well-defined circuit called covid-19 circuit, with limited access to positive patients, authorized personnel equipped in accordance with international recommendations (full blouse , visor, FFP2 mask and on shoes). This circuit has three hospital rooms, an operating room and a delivery room. This service is equipped with cameras and all the necessary logistics to limit the possible spread of the virus to other structures in the hospital. The only measure missing is maintaining negative pressure in the various rooms. Concerning medical and paramedical nursing staff, surface technicians, and logistics workers, the workforce has been reduced to the strict minimum with a rolling system and a recovery period, without forgetting an additional measure: the requisition of many hotels to accommodate covid nursing staff. Radiological exploration (Chest X-rays and Thoracic Scanners: low dose chest CT scan (between 0.01 and 0.66 mGy)) after abdominal protection (lead apron) as described in the literature (9) was carried out in only one patient (N ° 1), because she had a high viral load with a second control given its persistence at high rates despite two week treatment. Her pregnancy was unrecognized. Apart from this patient, radiological examinations was granted for patients presenting signs of severity or associating comorbid factors (In this series it was not necessary). Invasive explorations have not been indicated or performed, as recommended by litterature (10,11).

We decide to give the first-line treatment (Vit C, Paracetamol, and Zinc) only to asymptomatic patients. 2nd-line treatment (Vit C, Paracetamol, Zinc, Azithromycin, and Hydroxychloroquine (12,13 and 14) was reserved for symptomatic patients, of course without any contraindication and after a cardiological consultation + a normal electrocardiogram The 3rd-line treatment includes antiretrovirals (Lopinavir).

We, therefore, find ourselves with three groups of patients as has been clearly specified in table number 3:

One patient (10%) was hospitalized because of her high viral load despite the absence of signs of severity, with unremarkable CT scans. She started on the second-line treatment, but despite taking two weeks, she kept a high viral load, so it was agreed to give her an antiretroviral (Lopinavir), and the outcome was favorable.

Three patients (27%) took second-line treatment because they were symptomatic without signs of severity or comorbidity.

Seven patients (64%) took the first-line treatment because they were asymptomatic; these patients were recovered from contacts of symptomatic Covid 19 cases.

The evolution of the patients: A miscarriage (10%), two term deliveries (18%), and a premature delivery of 36 weeks with amenorrhea (10%). The other seven patients are still pregnant: three of them in the 2nd trimester, the other four are in the 3rd trimester. They have a regular medical follow-up and do not present any problem as well as their pregnancies. For the three patients who gave birth, only one had premature delivery at 36 weeks with a hypotrophy expected on a small growth retardation in utero diagnosed antenatally. (15,16 et 17) but without any hemodynamic impact on the newborn because a precautionary pulmonary maturation had already been carried out before birth by antenatal-corticosteroids administration (5), and the baby has been hospitalized for four days in the neonatal department as a safety measure. This spontaneous incident does not allow us to establish a ratio of 07 patients who have not yet given birth. All samples taken from the three babies were found to be negative (2, 5 et 15); of course, breastfeeding was authorized (15) with the precautionary measures for a single patient because she was still under treatment and had not yet negative its PCR (test of genomic amplification of the virus: Polymerase Chain Reaction) for the two others they were respectively negative for three weeks and two weeks already before the childbirth. The only patient who posed a problem for us was the patient who had a miscarriage at six weeks of amenorrhea, her pregnancy was unrecognized during the diagnosis of her Covid-19 infection, with no notion of delay in menstruation, and the patient was on 20 ug estrogen-progestogen pill contraception. She was not very symptomatic, but on the other hand, the high viral load persistence forced us to use first-line treatment, then second-line treatment and only after use of the anti-retroviral that we were able to have the cure but unfortunately, two weeks later she had a spontaneous miscarriage two days after the diagnosis of a stopped pregnancy dated by her obstetrician at six weeks and five days.

V. Conclusion

Unlike previous epidemics caused by other coronaviruses, this covid-19 pandemic does not appear to have consequences for pregnant women, apart from a maternal death described in the literature (18). In our series with the recovery of all our patients, the absence of repercussions in the three patients who gave birth except for the small growth retardation in uétro and the miscarriage (which may not be considered as a direct consequence of the covid -19 because we know that apart from any predisposing or aggravating factor, 15 to 20% of early miscarriages are due to chromosomal abnormalities) we can conclude that it is possible to take care of pregnant patients with covid- 19 on an outpatient basis, while considering our selfs happy and lucky because we are aware that although 75% of patients are paucisymptomatic, according to the literature, there would be 25% who could present moderate to severe respiratory distress (5) and that in

the face of epidemiological phenomena as exceptional and unpredictable as this, we have to be humble and stay on our guard especially with the second wave starting to emerge.

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Things that Must Not be done in Gynecological and Obstetrics

By Alejandro C. Ch. Siu-Au & Diego A. Siu-Chang
Universidad Peruana Cayetano Heredia

Introduction- After nearly forty-two years in practice, this is a short summary of experience from our institution and also from other centers; and, especially, incorporating experiences from other colleagues, so that the idea is to share valuable stories, circumstances, and knowledge. Therefore, this paper may become a source of reference as an aid when working in this quite demanding medical and surgical specialty.

The circumstances herein described may have occurred in many centers and institutions, and we must remember that communicating and sharing our experiences may prevent the occurrence of undesirable events.

This paper is an update of a previous article that was published nine years ago. New topics that are part of our current practice have been introduced and developed. Perhaps there are not many references since this is not a strict scientific document or a rigorous research project or a paradigmatic icon in Obstetrics and Gynecology. The decision for preparing and updating this paper was based on the generous reception it achieved in different academic meetings, including symposia of the Peruvian Gynecology and Obstetrics Society, our latest National Congress; and particularly, on requests made by many dear friends and junior specialists who are so eager to learn from the experience of us, senior practitioners.

GJMR-E Classification: *NLMC Code: WQ 400*

THINGSTHATMUSTNOTBEDONEINGYNECOLOGICALANDOBSTETRICS

Strictly as per the compliance and regulations of:

Things that Must Not be Done in Gynecological and Obstetrics

Lo Que No Se Debe Hacer En Ginecologia Y Obstetricia

Alejandro C. Ch. Siu-Au [α] & Diego A. Siu-Chang [σ]

Introduction

After nearly forty-two years in practice, this is a short summary of experience from our institution and also from other centers; and, especially, incorporating experiences from other colleagues, so that the idea is to share valuable stories, circumstances, and knowledge. Therefore, this paper may become a source of reference as an aid when working in this quite demanding medical and surgical specialty.

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For a proper start, the four cornerstones of modern medical ethics will be introduced (Belmont Report, April 18th, 1979) and then things that MUST NOT BE DONE in Obstetrics and Gynecology will be developed.

1. *No Maleficence:* This means never causing any deliberate harm to patients under our care.
2. *Autonomy:* This is our current model and now it is replacing the traditional paternalistic attitude within medical care. This allows patients to participate in the diagnosis, management and therapy processes. This ethics value was developed after the Second World War.
3. *Beneficence:* Our actions must be solely directed towards doing the best for our patients, aiming to achieve the best benefit for all of them.
4. *Justice:* All patients must be treated equal, no matter their social condition, religion, economic status or any other particular consideration.
5. *Coffee consumption:* It is not advisable the surgeon has an excessive intake of coffee, dark tea, or alkaloid containing energizing beverages or soft drinks, prior to a surgical procedure, particularly if delicate procedures such as microsurgery are to be performed. Most soda drinks contain caffeine. Alkaloids may exacerbate adrenalin and endorphin production and they reduce the capability for performing fine movements. A good choice is to drink decaffeinated coffee or caffeine-free soda (1), (2).
6. *Air exchange.* Never miss having air exchange in the Operation Room (OR), aiming to reduce and prevent infections. Exchange must consist of using 15 times the total environmental air volume for every hour we may spend in the OR. Good quality air extractors and air conditioning devices must be available. Surgeons performing open surgical procedures, or any other procedure type should not transpire, since there is likelihood that sweat droplets may reach the operative field (3), (4).
7. *Antibiotic prophylaxis.* This measure must not be abused. Many studies, including some performed in our institution have shown that in elective surgery, patients undergoing adequate pre-surgical preparation have the same likelihood for developing any infectious complication compared with those that had received antibiotic prophylaxis, including those undergoing vaginal or abdominal hysterectomy or those undergoing a cesarean section (5),(6),(7),(8). Antibiotic misuse or abuse leads to the development of multidrug-resistant microorganisms.

Author α: PhD, Gynecology and Obstetrics Specialist in Arzobispo Loayza National Hospital; Lima, Peru; Main Teacher, Gynecology, Obstetrics, and Reproductive Medicine Academic Department, Universidad Peruana Cayetano Heredia.
e-mail: alejandro.c.siu@gmail.com
Author σ: General Practitioner.

8. *NSAIDS in the immediate postoperative period.* Analgesic agents that may lead to coagulation alterations must not be used, at least during the first 24 hours after pelvic surgery. The use of opiate derivatives is a preferable choice. The rich venous network and abundant vascular plexuses in the pelvis must be considered, in which the only hemostatic action we could take is compress affected tissues, without using vascular ligation or cauterization.
9. *Appropriate dressing in the Operating Room.* Hair from the head and other areas, as well as the nose, must always be covered with a cap, mask, and gown. If exposed, hair may contaminate the surgical area and the immediate surrounding environment. Some female or male doctors misuse their caps by allowing some portions of their hair to be exposed, just as if they were participating in beauty contest; which may be a reflex of their own insecurity on their physical capability (and also intellectual disability?) for attracting the opposite sex. Sometimes, their nose is not adequately covered, and maybe they ignore the number of microorganisms currently residing in this area. The larger the nose is, the larger the number and presence of potentially pathogenic microorganisms. The Operating Room and the Surgical Center are not a place for having an affair. These are places for saving lives, and for alleviating and cure patients. The most serious situation is that such behaviors may constitute a negative paradigm for all involved personnel. We are healthcare professionals, independently of sex, and no matter how good looking we are or not.
10. *Seasonal or Occasional Infections.* No sick person(s) must be allowed to enter the Operating Room, even if they should have a mild cold, low-grade fever, or any suspiciously infected skin lesion.
11. *Wound Care.* Wound care must not be performed on infected patients before entering the Surgical Area. This activity must be performed at the end of the scheduled surgery day, or personnel that is not scheduled for any surgical procedure may perform surgical care. Everyone and everything are a potential infection source.
12. *Gloves during the Surgical Procedure.* Gloves generally come impregnated with powder, aiming to prevent adhesions or leaving debris in the surgical cavity which may lead to pyrogen generation and adherence enhancement. Do not forget to wash gloves with saline solution until every residue is eliminated. Glove washing must not be done using dextrose solution, since glove covered fingers and hands may become firmly fixed (9).
13. *Surgery times.* No time limits should be established when performing a surgical procedure. This may lead to apprehension, it may alter the surgeon's mood, it creates stress in participants and in all personnel. The anesthesiologist should be cautious should he/she request to shorten or hurry the surgical procedure. Being fast for performing any surgical procedure comes with practice. The fastest professional when operating is not necessarily the best in the field. Of course, there are some exceptions to the rule.
14. *Electrosurgical materials.* Do not miss checking up where the electrocautery plaques are placed. These may lead to severe burns in patients if they accidentally get wet or if inadequate contact is achieved.
15. *Heparin for helping with irrigation while performing videolaparoscopy.* In laparoscopic surgery, do not forget to use heparin in the irrigation fluid, this prevents the formation of clots that may obscure the surgical bed. Proper heparin use allows easy fluid and blood aspiration for adequately identifying structures. The likelihood for heparin anticoagulating the patient is nil, since a minimal dose is used, and it does not generate any systemic effect.
16. *The importance of bipolar forceps.* No endoscopic gynecological procedure should be done without having adequate spare bipolar forceps. These devices are so useful for hemostasis. Without their use, rates for conversion to laparotomy would be higher, with the consequent risk for patients.
17. *Menses during gynecological surgery.* No gynecological surgery procedure should be performed, whether open or laparoscopic if the patient is menstruating (do not consider cases of abnormal uterine hemorrhage), since problems with bleeding and hemostasis may become more severe, because of the physiological alterations occurring in the coagulation cascade during this time period in women of child-bearing age (10).
18. *Presence of a Foley catheter.* Do not forget to place a permeable Foley catheter in the urinary bladder during the whole surgical procedure. Therefore, lesions in an empty bladder are prevented, and the pelvic operative field is widened, reducing the likelihood for affecting structures like the ureter and the intestines, on top of the urinary bladder.
19. *Preoperative assessment.* No surgical procedure should be started without having previously met the patient and without having performed a thorough physical examination. This latter procedure defines the type of incision to be made, the procedure type, or withhold the surgical procedure because of an inappropriate indication. Many times, some surgeons operated patients assessed by other colleagues with indications for excising cysts or

fibromas; and when cavities were explored, none of such 'tumors' were found.

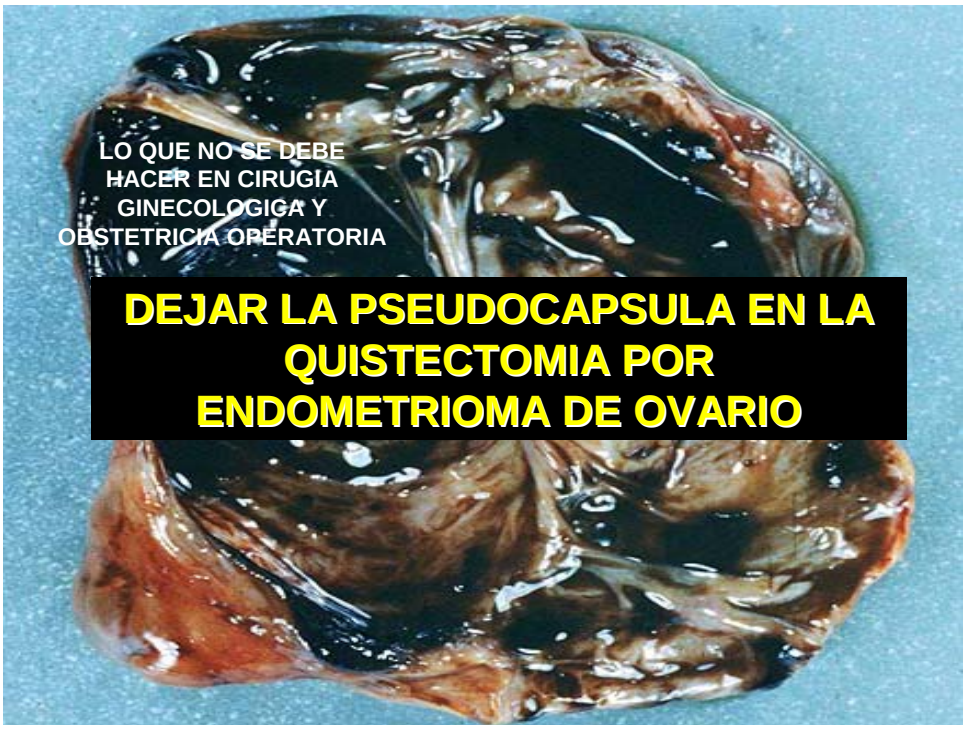
20. *Intravenous access for fluid administration.* No surgical procedure should be initiated without having a proper intravenous access. This is crucial for rapid fluid or blood replenishment. This is a lifesaving procedure.
21. *Patient relaxation.* A poorly relaxed patient must never be operated. We must request the anesthesiologist to have the patient completely relaxed, particularly for laparoscopic surgical procedures, unless it may be a matter of life or death. Having a patient perform Valsalva's maneuver during the surgical procedure where crucial steps are being taken, would not be feasible and it would be very risky for all.
22. *Introducing Veress needle.* The introduction of the Veress needle is to be taken so seriously when we are about to insufflate the abdomen and produce pneumoperitoneum for a laparoscopic surgical procedure. We must be so careful, since subcutaneous emphysema may occur, a blood vessel may be perforated, or an organ may be damaged.
23. *Adequate pneumoperitoneum.* The abdomen must never be inadequately insufflated when entering for the very first time in a blinded fashion while performing videosurgery. Insufflation must be adequately performed, or no insufflation is done, and then open surgery is to be performed. There are some reports of aortic perforation occurring in such circumstances (11).
24. *Gas from pneumoperitoneum.* Do not use oxygen or gases that may unfavorably affect patients when laparoscopic surgery is performed, even if they were less expensive. Oxygen is a good electricity conductor and it may inadequately conduce an electric spark. Other gases may compete for patient's oxygenation and lead to deleterious effects. The most adequate measure is to use carbon dioxide (12).
25. *Auxiliary instruments in videosurgery.* Auxiliary instruments, such as uterine manipulators, fixing forceps, separators or dual valves for irrigation must not be left apart. Some persons think that by using less instruments they might become better surgeons. They might be skillful, but they may not be working under comfortable conditions and then they may place patients at an avoidable risk. This arrogant act is against the principles of medical ethics. Adequate instruments for each circumstance must be properly used.
26. *Horizon when doing videosurgery.* When performing laparoscopic and hysteroscopic surgery, the horizon line and/or the tridimensional space must never be lost. We must demand that the cameraman follows the action maintaining these vital reference points. By doing so we will not lose the anatomical perspective and we will avoid having lesions in different organs and systems. Because of losing perspective and horizon, ureteral, bladder, and intestinal lesions have been reported. There have been cases in which bladder perforation has occurred, with invasion of the wide ligament, crossing the uterine wall.
27. *Dorsal aspect of Fallopian tubes.* When performing Fallopian tube surgery, it is important not to forget that the dorsal aspect of Fallopian tubes is the less vascularized area, and there is the place where the procedure may be safely performed.
28. *Usefulness of irrigators in videosurgery.* Do not forget that irrigators they also are helpful in dissection and not only for irrigation and aspiration. The technique is called hydrosection, and this must be mastered by every laparoscopy specialist (13).
29. *Abdominal incision in case malignancy is suspected.* No transversal incisions should be made when opening the abdomen when there is strong suspicion on the presence of a malignancy. Cancer staging or cytoreduction may become more difficult by doing so.
30. *Gauze in surgery.* Folded gauze packages must not be opened, since small pieces of thread may be left in the abdominal cavity, and these materials may become pyrogenic compounds. These should never be dragged when cleaning the area, since they may cause lesions in vascular structures and enhance the formation of adhesions.
31. *Gauze in microsurgery.* Never use dried gauze when performing microsurgery procedures. Gauze should always be humidified for use, even when solely used for hemostasis.
32. *Aid in videosurgery.* When performing laparoscopic surgery and microsurgery, you should never operate with an assistant that might have no idea of the anatomical area to work with and/or who is poorly trained. This becomes of paramount importance when they are starting their learning curve.
33. *Coagulation and cauterization in Endoscopic Surgery.* When working in endoscopic surgery, blood vessels and tissues must not be sectioned without prior cauterization. Should this not be the case, these structures may bleed and sometimes it is so demanding to stop all bleeding.

- Cut Down Tissues or Vascular Pedicles During Endoscopy without Having Performed Electrocoagulation
- Dissect Tissues without Having Identified Cleavage Planes.

34. *Dissection planes.* Do not leave cleavage planes unidentified. Otherwise, dissection may become difficult with plenty of bleeding.
35. *Septic foci when performing high-complexity fertilization procedures.* Septic foci in laparotomy (hydrosalpinx, ovarian microabscesses) must never be left when performing laparotomy prior to a high-complexity fertilization procedure. These structures or tissues are embryotoxic, they maintain the presence of endorphins that reduce pregnancy viability (14).
36. *Hysterotomy while performing myomectomy.* No uterine corporal incisions should be made in case a myomectomy is performed. Transverse incisions are preferred since they lead to less bleeding and they also lead to less adherence formation. Although some cases have been reported where no transverse incision could be made, because of concern with respect to affect tubal ostia or because of the tumor localization.

- Myomectomy With No Transverse Incision
  - o Correct: Myomectomy With A Transverse Incision Using Videolaparoscopy
- Making Uterine Corporal Incision In Myomectomy
  - o Correct: Myomectomy With A Transverse Incision In Laparotomy

37. *Capsule of an Ovarian Endometrioma.* When doing endometrioma surgery, conventional or laparoscopic, the pseudocapsule or portions of the pseudocapsule must never be left. Recurrences of the disease will be higher. The whole pseudocapsule must be excised; if this is not possible, this structure will have to be destroyed using electrical ablation (15).



Leaving the Pseudocapsule when Performing Cystectomy Because of an Ovarian Endometrioma

38. *Endometriosis areas.* If endometriosis areas are being worked with, their destruction must not be superficial. Their whole depth implantation must be reached unless the implants are located upon a hollow viscus and risk of perforation may supervene. In such cases, management may incorporate complementary medical therapy (16), (17).
39. *Uterine tumors and videosurgery.* Do not intervene on uterine tumors that are extrapelvically located according to videosurgery, if no electric morcellator is available. Doing morcellation using a vaginal approach with such tumor means putting the patient at risk; and if a decision is made for using a vaginal approach, ad-hoc instruments must be readily available, including a special bayonet.
40. *Decision for conversion.* Neither folly nor silliness should prevail for deciding of converting a laparoscopic to an open surgical procedure. We must always think about the patient.
41. *Fallopian tube microsurgery.* We must never leave less than 4-cm of the Fallopian tube in case of performing reconstructive surgery. If in the projection the tube is less than 4-cm long, surgery must not be scheduled or attempted. Such tubes will never work, or they will be site for a future ectopic pregnancy (18).
42. *Simultaneous videosurgery procedures.* Do not miss combining hysteroscopic resection of deep seated myomas with simultaneous videolaparoscopy control, aiming to monitor the hysteroscopic procedure in order to prevent uterine perforation.
43. *Importance of anatomical markers.* We must not operate without knowing the anatomical markers of vascular, ureteral, and bladder crossings as well as those for all plexuses.
44. *Hypogastric or internal iliac ligation.* We must not miss the technique for hypogastric (blood vessels) ligation. Every pelvic surgeon who respects himself/herself must master the technique for locating and ligating hypogastric arteries. We must remember that these arteries downstream become uterine arteries. They are also known as internal iliac arteries and their anatomical marker is the obturator fossa or foramen, in the vicinity of the ureter.
45. *Washing the abdominal cavity.* Avoid not performing thorough washing of the abdominal cavity. Not less than 8-liter fluids or saline solution should be used when washing a cavity, especially if a perforation of a cystic teratoma had occurred, because of the risk for the development of chemical peritonitis. This washing procedure must be performed both in open surgery as well as in laparotomy.
46. *Surgical approach for an abdominal malignant tumor.* Videosurgery must never be performed when there is strong suspicion that the ovarian tumor (to be operated) is a malignant neoplasia. In such cases, an open procedure with a median incision is preferable.
47. *Preventing pelvic adhesions.* Because of not leaving enough fluid or because of leaving clot residues. When a small amount of fluid or clots are left in an unpolished surface, the generation of adherences is enhanced.
48. *Relationship between intraabdominal pressure with hemostasis.* Do not review hemostasis excessively reducing intraabdominal pressure when finishing a laparoscopic procedure. The intraabdominal pressure should be reduced to 7-mm Hg. With this level, collapse of both venules and arterioles that might bleed when taking cannulas and the laparoscope tube out is prevented.
49. *Reviewing the places where trocars are inserted.* We must never miss reviewing the places where intraabdominal trocars and cannulas for videolaparoscopy have been inserted when the procedure is over, in order to determine whether a hematoma had been formed or if there is any bleeding.
50. *Assessing the uterine cavity during hysteroscopy.* While performing a hysteroscopy we must never explore using optics or during the introduction. The exploration must always be performed taking out the optics, after reaching the end of the cervix we introduce the instrument once again until touching the uterine fundus, exploration is reinitiated, and the procedure is repeated as many times as necessary. By respecting this technique, we will avoid perforation accidents. Surgeons overestimating their capability are those who have accidents, that is not the case with those who recognize their limitations.

- Introduce Optics from the Cervix Towards the Uterine Fundus in Hysteroscopy During the Exploration

Correct: Always Vision from the Fundus towards the External Part

51. *Releasing uterine synechiae.* Uterine synechiae must not be released using curettes. Uterine synechiae must be released using an adequate resectoscope for such circumstance during direct vision hysteroscopy, and it is much better to have appropriate scissors available.
52. *Time for correcting cystocele during TOT suspension.* Perform TOT (Trans obturator Tape) suspension not having corrected cystocele (19). Emmett needles must never pass through the obturator fossa for sling placement, without previously having corrected urinary bladder prolapse, since likelihood for having urinary bladder perforation is increased; also, it will be more difficult to establish the ideal stress aiming to suspend the ureterocele with a sling or a mesh in order to avoid stress urinary incontinence.
53. *Fetus in transverse dorsal anterior position with premature membrane rupture.* Transverse hysterotomy must not be done in those cases showing the fetus in a transverse position with its dorsal part facing forward and membrane rupture. The likelihood for failure when attempting fetus extraction is so high and the incision would have to be extended or another incision might be performed. The likelihood for tearing the uterine segment and hemorrhagic complications is much higher. There have been reported cases that ended in hysterectomy. The adequate procedure is to perform corporal hysterectomy.
54. *Suprapubic amniocentesis in preterm pregnant women.* Suprapubic amniocentesis must not be performed in preterm pregnant women. This procedure should be done using other approach and always under ultrasonography guide. If a suprapubic puncture is performed, the likelihood for premature membrane rupture is very high.
55. *Forceps, vacuum, and cervical dilatation.* Forceps or vacuum must never be used if the cervix is not completely dilated. The likelihood for the occurrence of cervical and segmental tearing is increased, and the baby may get hurt (20).
56. *Forceps, vacuum, and pelvis.* No instrument must be used (for delivery) if you are not sure the pelvis is gynecoid and there is no fetal-pelvic disproportion (20).
57. *Breech presentation in a first-time mother.* Breech delivery in a first-time mother must not be managed without proper assistance. Adequate assistance is necessary for performing the appropriate maneuvers. By this, we may obtain a less-affected baby.
58. *Forceps type for each situation.* Any forceps type must not be used for any circumstance. Each forceps type has its own indications. Simpson is for fetuses with molded head occurring in first-time mothers, Elliot is for fetuses with non-molded head occurring in multiparous women. McLean is a non-fenestrated forceps to be used with premature babies since it protects their head from contacting

vaginal walls. Piper is for breech presentations in case of last head, and Kielland is a rotating forceps.

59. *Piper Forceps Placement.* Piper forceps must never be used by a single professional. You must always use this instrument with proper assistance. The technique for its use requires so (20).

Piper Forceps Placement without Proper Assistance

60. *Presence of an assistant:* No gynecological examination should be performed without the presence of an assistant. By doing so, you may avoid any demand because of sexual harassment or the like.

61. *Dressing style.* No informal dressing should be used since this may lead to confusion and it may generate uncomfortable situations with the patient and/or her relatives. Gynecology and Obstetrics

specialists must always dress properly, emphasizing their physician status.

62. *Equivocal situations:* Equivocal situations that may mean harassment must never occur during the visit, whether the patient comes alone or with her spouse.
63. *Conversations during the visit:* Only strictly professional topics must be dealt with. If other non-medical issues are to be talked about, this will take place once the consultation is over, understanding that the patient already knows this is so.
64. *Guaranteeing success when managing infertility cases:* When treating a couple that is asking for In vitro Fertilization (IFV) + Embryonic Transfer (ET) and/or intracytoplasmic sperm injection (ICSI), you must never miss insistently informing success and failure rates, as well as the likelihood for the occurrence of congenital malformations and defects (21),(22).
65. *Risks in pre-implantation studies:* If the patient requests a pre-implantation genetic diagnosis, mentioning risks when taking the cells for study must never be missed (23), (24), (25).
66. *Informed consent:* Never miss explaining the procedure stating all its benefits and consequences; also, make the patient and her spouse sign the informed consent before performing any intervention (26), (27).
67. *Voluntary withdrawal:* If at any time while the patient is hospitalized, she refuses any procedure of therapy; it is important not to sign her discharge; instead, prepare a 'voluntary withdrawal' document to be signed by the patient in the presence of witnesses. Therefore, when the physician discharges the patient, it is under her responsibility (28), (29).
68. *Covid-19 pandemics:* It is important to comply with social distancing, properly using a face mask and to constantly wash your hands (30), (31).
69. *Social distancing for physical examination in the Covid-19 pandemics:* It is not possible to comply with physical examination for all patients. Therefore, we must NOT receive patients with fever, those reporting contact with Covid-19 affected people during the last two weeks prior to the visit, those not using a face mask or those who may present with an evident NON-gynecological physical involvement (30), (31).
70. *Asymptomatic pregnant women with Covid-19:* We must never forget that there may be a significant number of pregnant women that might have asymptomatic Covid-19 infection (32), (33), (34).
71. *Vaporizer use, Covid-19:* Prior to the consultation, it is convenient to vaporize patients with fifth generation quaternary ammonium for sixty seconds. This compound may eliminate viruses, bacteria, and fungi.
72. *Personal protection equipment withdrawal:* DO NOT FORGET that the moment with a maximum likelihood for transmission occurs when taking out the protective equipment, such as face protectors, gloves, coats, face masks, etc. (30).

So, we reached the end of this paper. Anyway, we are so happy that we did not find further data in our reference and experience bank. We hope this paper is helpful for you and especially for patients, who still are our reason for doing a good job.

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Relation of High Maternal Body Mass Index to Perinatal and Maternal Outcome

By Dr. Khushboo Patel & Dr. Smita Baheti

Abstract- *Background:* Worldwide, obesity is the prevalent, chronic medical condition. Maternal body mass index (BMI) is one of the predictors of the nutritional status of pregnant ladies. Obesity influences not only the chance of conception but also reduces the response to fertility treatment and increases the risk of miscarriage, congenital anomalies and pregnancy complications like gestational diabetes, pregnancy-induced hypertension, cesarean delivery, macrosomia, and affects health of both mother and newborns.

Methods: Following approval from Institutional Research Ethical Board and written informed patient consent, this study has been conducted at Geetanjali Medical College and Hospital (GMCH) Udaipur from January 2019 to January 2020.

Results: One hundred and fifty pregnant women with high BMI >25 kg/m2 were selected and were followed prospectively. Present study showed an increased incidence of pre-eclampsia in patients with high BMI 61.1% and a higher incidence of Gestational diabetes mellitus among women with high BMI with a value of 38.9%. in present study there was increasing incidence of preterm labor among BMI more than and equal to 35 patients 77.8%.

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Conclusions: Obese mothers have more risk of preterm LABOR and preeclampsia, caesareans. Babies with high maternal BMI have high risk of IUGR, preterm birth, low APGAR score at birth, low birth weight and high NICU admissions.

I. Introduction

Worldwide, obesity is the prevalent, chronic medical condition [(1)]. The rate of obesity in pregnant women is rising, increasing the significance of its impact on obesity-related pregnancy complications. [(2)]

Maternal body mass index (BMI) is one of the predictors of the nutritional status of pregnant ladies. The problem of rising obesity is not unique to India. In earlier research, the relationship between maternal height and weight with pregnancy complications have been extensively explored, but in recent times, BMI is widely accepted as a better measure of over or underweight [3].

Most of the developing countries, including India, are now facing double burden because of extreme socioeconomic distribution. On one side, there is overweight and obesity which has reached epidemic proportions and on the other side, there is underweight and undernourishment. In India, 26% of pregnant women are overweight, and 8% are obese [(4)].

Obesity influences not only the chance of conception but also reduces the response to fertility treatment and increases the risk of miscarriage, congenital anomalies[(5)] as well as pregnancy complications like gestational diabetes, pregnancy-induced hypertension, cesarean delivery, macrosomia, and infections in addition to potential adverse effects on long term health of both mother and infant[(6)]

The World Health Organization [(7)] and the National Institutes of Health [(8)] define normal weight as a BMI of 18.5–24.9,

overweight as a BMI of 25–29.9

obesity as a BMI of 30 or greater.

Obesity has further been characterized by BMI into Class I (30–34.9), Class II (35–39.9), and Class III (greater than 40).

An increased association of morbidity and mortality with obesity is well established in both pregnant and nonpregnant women. [9] Pregnancy with obesity is considered as high risk, and it causes substantial feto-maternal morbidity and mortality. Hence the purpose of this study was to examine the association between high BMI and feto-maternal outcome in primigravida women delivering singleton babies.

II. Aim & Objectives

a) Aim

To find out the effect of high body mass index on pregnancy outcomes and perinatal outcomes in nulliparous women delivering singleton babies.

b) Objective

- To determine the maternal risk in terms of antepartum, intrapartum, and postpartum complications about maternal BMI.
- To determine the perinatal outcome about high maternal BMI.

III. Material and Methods

Following approval from Institutional Research Ethical Board and written informed patient consent, this

Author α σ: e-mails: khushboodr81.kp@gmail.com, smitasomani123@gmail.com

study has been conducted at Geetanjali Medical College and Hospital (GMCH) Udaipur from January 2019 to January 2020.

Study area- department of obstetrics and gynecology of GMCH, Udaipur

Study design- A longitudinal observational study

Source of data– All the antenatal patients attending OPD and admitted to GMCH from January 2019 to January 2020.

Inclusion criteria–

- Patients who give consent for the study
- Women with singleton pregnancies with high BMI (> 25)
- Booked cases with their first visit before 12 weeks of gestation.

Exclusion criteria-

- Women with multiple pregnancy
- Congenital malformation in the fetus
- Women with pre-existing medical disorders.

a) Methodology

After obtaining approval from the Institutional research Ethical board and written informed patient consent, this study was conducted at Geetanjali Medical College and Hospital Udaipur from Jan 2019 to January 2020.

Cases were taken from the obstetrics and gynecology department attending the OPD and admitted in maternity having high BMI. Detailed history and examination, height, weight and co morbidities were documented with the help of Performa. Women were followed up till deliveries, and their babies were followed up till discharge from the hospital. Various maternal, fetal, and perinatal outcomes were observed in this observational study.

b) Proposed Statistical Analysis

Analysis of collected data was done on based of statistical tools and techniques. Data was presented in the form of tables, and charts and graphs such as bar diagrams and pie charts. Analysis of data will be done on based of inferential statistics and descriptive statistics, whatever is required to fulfill the objective.

c) Statistical Analysis

The collected data was cross-checked and entered into Microsoft Excel Software and was exported to SPSS, IBM Inc version 21 for statistic analysis.

IV. Results

Total of 150 primigravida patients of single tone pregnancy with BMI more than or equal to 25 Kg/metre2 were included in our study, and divided these patients into three groups having BMI 25-29.9 (group 1), 30-34.9(group 2), and more than and equal to 35(group 3).

Table 1: Age-wise distribution

	Age group (years)			
BMI Group	21-30	31-40	41-50	Total
25-29.9	63 (67.7%)	24 (25.8%)	6 (6.45%)	93 (62%)
30-34.9	23 (58.9%)	16 (41.0%)	0 (0%)	39 (26%)
>35	11 (61.1%)	5 (27.7%)	2 (11.1%)	18 (12%)
Total	97 (64.7%)	45 (30%)	8 (44.4%)	150

p=0.203 (NS)

In our study we found maximum patients of BMI 25-29.9 among 21 to 30 years of age.

Among 150 patients 93(62%) fall in 25-29.9 kg/metre^2 BMI group, 39(26%) in 30-34.9 BMI group and 18(12%) in more than and equal to 35 BMI group.

For BMI 25-29.9 group, 67.7% of patients from the 21-30 years age group.

For BMI 30-34.9 group maximum 58.9% patients were from 21-30 years age group.

For BMI more than and equal to 35 groups again maximum of 61.1% patients from 21-30 years age group (table 1).

Table 2: APGAR SCORE

	BMI Group			
	25-29.9	30-34.9	>35	Total
APGAR <9	47 (50.5%)	31 (79.5%)	17 (94.4%)	95 (63.3%)
APGAR =9	46 (49.5%)	8 (20.5%)	1 (5.6%)	55 (36.7%)
Total	93	39	18	150

p<0.001 (HS)

Among 150 newborns of 150 mothers of BMI more than or equal to 25, we found 95 newborns, having APGAR at one minute of birth was less than 9.

Among 39 obese mother' newborns 31(79.5%) had APGAR less than 9

Among 18 BMI more than or equal to 35mothers' newborns, we found 17(94.4%), newborns. With low APGAR which was highly significant with a p-value of < 0.001(table 2).

Table 3: Maternal Complications

Table 3: Complications of pregnancy and their relationship with BMI during early pregnancy

	BMI Group				
Complications	25-29.9 (n=93)	30-34.9 (n=39)	>35 (n=18)	Total	p value
Mode of delivery (LSCS)	8 (62.4%)	24 (61.5%)	14 (77.8%)	96	0.429
GDM	17 (18.28%)	6 (15.4%)	7 (38.9%)	30	0.095
Pre-eclampsia	34 (36.6%)	25 (64.1%)	11 (61.1%)	70	0.006
PRETERM LABOR	36 (38.7%)	26 (66.7%)	14 (77.8%)	75	0.001
Macrosomia	17 (18.3%)	6 (15.4%)	7 (38.9%)	30	0.095
Oligohydramnios	18 (19.4%)	5 (12.8%)	0 (0%)	23	0.100
GHTN	49 (52.7%)	13 (33.3%)	3 (16.7%)	65	0.006
Anemia	38 (40.9%)	23 (60%)	3 (16.7%)	64	0.009

In our study, we found a high incidence of GDM in BMI more than or equal to 35patients with BMI more than or equals to 35 kg/metre^2 (38.9%), but it was not statistically significant.

Incidence of preeclampsia was high among more than or equal to 35 BMI group (61.1%) with p Value of 0.006, which suggest it is highly significant.

The present study showed the increasing incidence of preterm labor among BMI more than and equal to 35 patients 14 out of 18 patients (77.8%) with a p-value of 0.001 which suggested strong association between high maternal BMI and preterm labor.

The present study showed a high incidence of macrosomia among BMI more than or equal to 35mothers (38.9%), which was not statistically found significant.

Current study showed more cases of gestational hypertension among the BMI 25-29.9 group (552.7%) and less among BMI more than or equal to 35 patients of 16.7%, which was statistically significant.

We found a 40.9% incidence of anemia in overweight patients compared to that 16% among BMI more than or equal to 35mothers (table 3).

Table 4: Birth weight and BMI

	BMI Group			
Birth weight (Kg)	25-29.9 N=93	30-34.9 N=39	>35 N=18	Total
<2.5	43 (46.2%)	30 (76.9%)	15 (83.3%)	88
2.5-4	40 (43%)	7 (17.9%)	2 (11.1%)	49
4-5.5	10 (10.8%)	2 (5.1%)	1 (5.6%)	13
Total	93	39	18	150

p=0.003

Table 4 shows the association between maternal high BMI and birth weight of the newborns.

Among all mothers hiving high BMI, the incidence of low birth weight baby was 58.7%.

Incidence of low birth weight is higher in BMI more than or equal to 35group (83.3%) whereas 76.9% among obese mothers and 46.2% in overweight mothers were found in our study. Which is having p-value 0.003, and so it was statistically highly significant.

Table 5: Neonatal Outcome

	BMI Group				
Neonatal Outcome	25-29.9 N=93	30-34.9 N=39	>35 N=18	Total	p value
IUGR	40 (43%)	22 (56.4%)	14 (77.8%)	76	0.018
NICU Admission	44 (47.3%)	31 (79.5%)	17 (94.4%)	101	<0.001
Mortality	4 (4.3%)	0 (0%)	1 (5.6%)	5	0.388

Table 5 shows neonatal outcomes and their relation with maternal BMI.

The present study showed 40 IUGR babies among overweight mothers (43.01%), 22 among obese mothers (56.4%), 14 among BMI more than or equal to 35mothers (77.8%).Which is statistically significant with a p-value of 0.018.

The present study showed maximum NICU admission of newborns among BMI more than or equal to 35 patients (94.4%), which was statistically highly significant with p-value less than 0.001.

In our study, we found four mortalities of baby among overweight mothers, o mortality among obese and one mortality among BMI more than or equal to 35mothers. It was found mortality occurs independently of maternal BMI and was statistically not significant (Table 5).

V. Discussion

In our study, we found the maximum number of patients from 21 to 30 years of age group 64.7%, 30% from 31 to 40 years of age, and 8% from 41 to 50 years. We found the maximum number of patients in the overweight group. We didn't find a significant association between age and BMI. That may be because, as age advances the reproductivity decreases[10].

In our study, we found a low APGAR score in the newborns as maternal BMI advances. Kumar HSA et al, 2017[11] have similar results.

In our study, we found a strong association of maternal complications like preeclampsia with maternal BMI more than or equals to 35 kg/metre^2.Which is like Doi L et al. [12] 2020 results.

We found a high incidence of preterm labor among mothers hiving more than or equal to 35 BMI which is comparable with Vinturache A et al, 2017 study[13].

In our study, we didn't get a significant association between a high maternal BMI and caesarean rates but overall LSCS rate was high in our study. Pettersen-Dahletal[14]. The study showed a high incidence of caesarean section among overweight and obese compared to normal and underweight those were 23.2 and 29.1%, respectively. In our study, we found much more 62.4 and 61.5%, respectively.

We found a significantly rising incidence of low birth weight babies among BMI more than or equal to 35mothers 83.3%. which is similar to Takai et al, 2017[15] results which may be due to dysregulation of pro-inflammatory cytokines as well as increased risk of infection in obese and overweight individuals as they will lead to reduced placental surface area and also their vasculature with consequent uteroplacental insufficiency[16]

In our study, we found more incidence of IUGR and NICU admissions in the BMI group more than or equal to 35, which is like Shah PM et al 2018 results [17].

VI. Conclusion

Through this study, it has been concluded that obese mothers have more risk of preterm LABOR and preeclampsia. Babies with high maternal BMI have high risk of Intra uterine growth retardation, preterm birth, low APGAR score at birth, low birth weight and high NICU admissions. Overall, patients have high risk of cesarean section. As obesity is modifiable and preventable, preconception counseling, weight loss before conception, diet and lifestyle modification before and during pregnancy, and creating awareness regarding associated health risks are highly required.

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Features of Somatic Anamnesis and Reproductive Function in Women with Uterine Myoma and / or Adenomiosis and Methods of their Correction

By Guldjahon S. Babadjanova, Sitora I. Abdurahmanova & Nigora D. Muratova

Introduction- Among the structural abnormalities in gynecology, uterine fibroids and adenomyosis are two different, although often coexisting pathologies with a noticeable prevalence in women of reproductive age. So far, various mechanisms have been proposed to explain the effect of each of these diseases on a woman's reproductive function. Modern data indicate that the presence of submucosal and intramural nodes of fibroids in the uterus has an adverse effect on conception and early pregnancy. In addition, the presence of fibroids is associated with adverse pregnancy outcomes. As for adenomyosis, apart from the supposed coexistence of adenomyosis and infertility, until now the causal relationship between these conditions has not been fully confirmed. However, preterm labor and premature rupture of membranes, rupture of the uterus, postpartum hemorrhage due to uterine atony and ectopic pregnancy have all been associated with adenomyosis [21].

Keywords: *uterine fibroids, adenomyosis, somatic morbidity, reproductive losses, childbirth, ultrasound and Doppler blood flow of myoma and adenomyosis nodes, modulators of progesterone receptors, dienogest.*

GJMR-E Classification: *NLMC Code: WP 660*

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Guldjahon S. Babadjanova [α], Sitora I. Abdurahmanova [σ] & Nigora D. Muratova [ρ]

Keywords: uterine fibroids, adenomyosis, somatic morbidity, reproductive losses, childbirth, ultrasound and Doppler blood flow of myoma and adenomyosis nodes, modulators of progesterone receptors, dienogest.

I. Introduction

Among the structural abnormalities in gynecology, uterine fibroids and adenomyosis are two different, although often coexisting pathologies with a noticeable prevalence in women of reproductive age. So far, various mechanisms have been proposed to explain the effect of each of these diseases on a woman's reproductive function. Modern data indicate that the presence of submucosal and intramural nodes of fibroids in the uterus has an adverse effect on conception and early pregnancy. In addition, the presence of fibroids is associated with adverse pregnancy outcomes. As for adenomyosis, apart from the supposed coexistence of adenomyosis and infertility, until now the causal relationship between these conditions has not been fully confirmed. However, preterm labor and premature rupture of membranes, rupture of the uterus, postpartum hemorrhage due to uterine atony and ectopic pregnancy have all been associated with adenomyosis [21].

In recent years, many scientific studies have been devoted to adenomyosis and uterine myoma, but the etiology and pathogenesis of these diseases have not yet been fully understood. Also, a combination of these two diseases has been increasingly diagnosed recently [19].

Author α: MD, Professor of the Department of Obstetrics and Gynecology #1, Tashkent Medical Academy, Almazar dist. Farabi str. 2, Tashkent, Uzbekistan. e-mail: babadjanova@mail.ru
Corresponding Author σ: PhD, Department of Obstetrics and Gynecology #1, Tashkent Medical Academy, Almazar dist. Farabi str. 2, Tashkent, Uzbekistan. e-mail: sitorababayeva@yandex.ru
Author ρ: MD, Associate Professor of the Department of Ophthalmology with the course of gynecology, Tashkent State Institute of Dentistry, Yashnabad district, Mahtumkuli str. 103, Tashkent, Uzbekistan. e-mail: muratova-84@mail.ru

Today, adenomyosis is considered to be an estrogen-dependent disease characterized by invasion of the glandular and stromal components of the basal layer of the endometrium into the myometrium. Studies have shown that with adenomyosis, the endometrium is characterized by a reduced sensitivity to progesterone and this contributes to the spread and survival of endometrioid heterotopias. The study of the pathogenesis of adenomyosis showed that endometrial cells can penetrate and multiply in the myometrium, and inflammatory mediators are involved in the development of intense pain syndrome [8].

It should also be noted that adenomyosis is characterized by an increase in neoangiogenesis and is important for the process of implantation of the glandular tissue of the endometrium in the pathogenesis of the development of adenomyosis [14]. Heavy menstrual bleeding and dysmenorrhea are the main complaints in women with symptomatic adenomyosis, but their etiology is not well understood. Some studies have shown that tissue factor (TF) is activated in endometriosis and menstrual bleeding in women is associated with long-term progestin-only contraception [15]. The authors believe that TF is involved in the development of adenomyosis associated with heavy menstrual bleeding and dysmenorrhea and, therefore, may be a potential therapeutic target in the treatment of symptomatic adenomyosis and possibly chronic pelvic pain in women with adenomyosis.

At the beginning of the century, researchers discovered some pathogenetic features of endometriosis / adenomyosis, in particular, the formation of anti-endometrioid antibodies (AEAB) in the blood of patients with endometriosis was described. A correlation was found between circulating AEAB and surgically confirmed endometriosis. The authors suggest that AEAB interact with some antigens that are associated with infertility, implantation disorders, and early miscarriages [2].

In turn, the pathogenesis of uterine fibroids is based on impaired progesterone synthesis, an increase in progesterone receptors in the myomatous nodes [4, 9]. The disease is characterized by various symptoms

such as dysmenorrhea, pelvic pain, dyspareunia, abnormal uterine bleeding and infertility. Uterine fibroids or uterine leiomyoma is the most common benign tumor of the uterus in women of fertile age, although the etiological factors have not been fully identified. The onset and development of fibromatosis may be associated with certain risk factors and gene mechanisms, although the exact causes are not yet fully known. The development of uterine fibroids correlates not only with metabolism and with the level of female sex hormones, estrogen and progesterone, but also with the amount of these hormone receptors expressed on the myometrium surface. The proliferative effects of estrogen and progesterone can be mediated by proinflammatory factors (TNF-alpha), growth factors (IGF1, IGF2, TGFbeta3, and beta FGF), or apoptosis inhibitors (p53 suppression). In about 40% of cases, uterine fibroids are caused by the same cytogenetic changes that have been found in other types of tumors such as kidney, lung, or leiomyosarcoma. As part of systemic dysfunction, uterine fibromatosis has been associated with other disorders such as AHT (arterial hypertension), endometrial adenocarcinoma, adenomyosis, endometriosis, diabetes mellitus, breast tumors, and common causation [16]. An important role in the development of these diseases is played by a somatic anamnesis, diseases suffered during the life, especially of an infectious and inflammatory nature, disorders of the nervous system, and others [12]. Some studies are devoted to the influence of impaired reproductive function of women on the development of fibroids or adenomyosis [21].

The action and influence of some types of hormonal imbalance in certain organs depends on the histological and local features of the expression of various receptors, which are the cause of many disorders, including uterine fibromatosis, which coexists or accompanies these disorders later [16]. Consequently, sex steroids are involved in the regulation of the growth of uterine fibroids, and in adenomyosis - the invasion of the endometrium into the myometrium, by acting on steroid receptors and the inclusion of cytokines and growth factors, determining the intensity of cell proliferation, apoptosis and angiogenesis [4].

To date, the improvement of non-invasive methods of ultrasound diagnostics with color Doppler hysterosonography and magnetic resonance imaging (MRI) can improve the accuracy of diagnosing the combined pathology of uterine fibroids and adenomyosis. The effectiveness of treatment of patients with a combined form of uterine fibroids and adenomyosis depends on the determination of the severity of a particular disease [1, 11, 13].

Today, one of the key treatment standards is considered to be a drug containing dienogest, which is a fourth-generation progestogen with selective activity of 19-nortestosterone and progesterone. Dienogest differs from other drugs in its powerful progestogenic activity, as well as in its pronounced antiestrogenic effect at the local level. Also, the drug has antiestrogenic, antiproliferative, anti-inflammatory, antiangiogenic effects and normalizes local immune disorders. The antiproliferative effect of dienogest (DNG) is closely related to its anti-inflammatory effect. DNG has no ethynyl radical and is metabolically neutral, which is extremely important for long-term therapy. A reliable antiovulatory effect due to apoptosis of granulosa cells of the dominant follicle is combined with a weak central effect (inhibition of FSH and LH levels) and a moderate decrease in the level of systemic estradiol, which is one of the special advantages of this drug. This drug, like other hormonal drugs, has no side effects such as estrogen deficiency, i.e. does not cause hot flashes, bone loss, does not increase the risk of cardiovascular disease. DNG reduces the level of ovarian production of estradiol only within the therapeutic window, which does not lead to an increase in endometrial proliferation, but avoids the development of symptoms of estrogen deficiency (hot flashes, bone loss and an increased risk of cardiovascular disease). Numerous clinical studies have shown that DNG at a dose of 2 mg / day successfully relieves pain caused by endometriosis (adenomyosis): dysmenorrhea, dyspareunia, premenstrual pain and pelvic pain. [3].

Previously existing contraindications such as the size of the uterus more than 12 weeks of pregnancy, submucous location of the node and its centripetal growth, the combination of uterine fibroids with ovarian tumors, in the case of rapid growth, suspicion of sarcomatous degeneration or malnutrition of the node, menometrorrhagia, causing severe anemia, however, today with the advent of the drug ulipristal acetate for the conservative treatment of uterine fibroids, the list of these contraindications has decreased.

Ulipristal-acetate is a selective progesterone receptor modulator (SPRM), its use allows us to offer various schemes of conservative drug therapy. Initially, the drug was proposed as a medication for the preoperative preparation of patients with uterine myoma [7, 18]. In international studies, it has been proven that ulipristal acetate modulates the number of progesterone receptors, thereby contributing to a decrease in proliferative processes in the myometrium and an increase in apoptosis [20]. By such actions, the drug leads to amenorrhea in patients with menometrorrhagia and increases hemoglobin, reduces the size of large nodes. The results of using the drug at 5 or 10 mg daily for 3 months showed that after taking the drug, the size of the nodes decreased significantly, and blood loss during the operation decreased due to the facilitated enucleation of the nodes. Drug efficacy studies have been compared with GnRH agonists and placebo [9]. Scientists noted that treatment with ulipristal acetate compared with a-GnRH has a more favorable course,

because it does not cause signs of hypoestrogenemia in patients, while the level of estrogen remains at the level of the middle folliculin phase.

Subsequent studies have proven its effectiveness not only for preoperative preparation, but also for conservative therapy without any surgical intervention, regardless of the location, number and size of nodes [5, 10]. On the effectiveness of the drug ulipristal acetate in the treatment of fibroids, 38 academic studies were carried out in scientific centers in Europe, and since February 2012, the drug (esmia) has been approved in the European Union for use in the treatment of uterine fibroids [6, 17]. And since 2014, ulipristal acetate has been approved for use in the treatment of uterine fibroids in Uzbekistan.

Analysis of modern literature has shown that in recent years, progress has been achieved in the treatment and diagnosis of uterine fibroids and adenomyosis in an isolated form. However, there are not so many studies on the combination of these two pathologies in the scientific literature, especially concerning research on diagnosis and treatment. So, if at the end of the last century the most effective method of treating these diseases was a radical operation and the issue of etiology, pathogenesis was considered already resolved, now it is shown the need to continue research by using new methods of diagnosis and treatment, because organ-preserving tactics are preferred.

Thus, a fairly large number of methods for invasive and non-invasive radical and non-radical surgical treatment of uterine fibroids and adenomyosis, both in isolated form and in combination, have been proposed. However, to date, there is no clear picture of the selection criteria and the optimal use of one or another method of treating combined pathology. A more differentiated approach to the choice of treatment tactics for each specific patient, taking into account her age, clinical picture of the disease, depending on the woman's reproductive function, is needed. This will reduce the frequency of radical surgical interventions, especially in women of reproductive age.

A new direction in the conservative treatment of uterine fibroids is the use of ulipristal acetate, which is a selective modulator of progesterone receptors, in adenomyosis, the fourth generation dienogest drug with selective activity of 19-nortestosterone and progesterone. Research conducted across Europe on the use of these two drugs for the treatment of fibroids and adenomyosis confirms its effectiveness. However, combined pathology requires further study of the issues of etiology and pathogenesis in the light of new scientific research. For combined pathology, standards for the treatment of women have not been developed, depending on age, combination characteristics, severity of clinical manifestations, growth and proliferative activity of myomatous nodes, the nature of adenomyosis and reproductive function.

The aim of the study was to study reproductive disorders and pregnancy outcomes in women with combined pathology of uterine fibroids and adenomyosis and to determine the effectiveness of methods of their drug correction.

II. Material and Research Methods

There were examined 75 women with a combined form of uterine fibroids and adenomyosis (group 1), 47 women with adenomyosis (group 2) and 43 women with uterine fibroids (group 3), the control group consisted of 21 healthy women. The studies were carried out on the basis of the Department of Obstetrics and Gynecology of the Tashkent Medical Academy in the gynecological department of the city maternity complex No. 9 in the period March 2018 - December 2019.

All patients had a thoroughly collected reproductive history (the number and outcomes of pregnancies: childbirth, artificial abortions, spontaneous miscarriages, non-developing pregnancy, infertility and its duration). All patients underwent ultrasound examinations.

In addition to reproductive disorders, we also studied the anamnesis of previous diseases (childhood infectious diseases, inflammatory diseases of the upper respiratory tract, ARVI, influenza) and currently existing chronic somatic diseases.

The examination of patients included a routine general examination, gynecological examination, ultrasound examination with the determination of the location and size of the nodes, determination of the presence and degree of adenomyosis. At the same time, a Doppler study of blood flow in the uterine arteries and vessels around and inside the myomatous node was performed with the determination of the resistance index (RI). This made it possible to determine the simple or proliferating type of myoma node.

III. Research Results and their Discussion

An analysis of previous diseases and currently existing somatic diseases showed that most of the patients had two or more diseases in the anamnesis. So, for example, 68% of patients in group 1 (with a combination of uterine fibroids and adenomyosis), 57.5% of patients in group 2 (with adenomyosis) and 61.7% of patients in group 3 (with uterine myoma) suffered two or more different somatic or infectious diseases.

Of the previously transferred diseases, attention is drawn to the high frequency of childhood infectious diseases (measles, rubella, chicken pox, mumps), 62.7% of patients in group 1 and 61.7% of patients in

group 2 in childhood suffered various infectious diseases (p <0.05). In group 3 patients, childhood infectious diseases were 1.7 times less common than in the first and second groups - 37.2% (p <0.001). Infectious hepatitis, on the contrary, was most revealed in group 1 with uterine myoma - 39.5% (p <0.001), and in patients with adenomyosis, infectious hepatitis was detected 2 times less often - 17.02% (p <0.01).

Diseases of the upper and lower respiratory tract (tonsillitis, tonsillitis, bronchitis, ARI, etc.) suffered from 90.7% to 95.7% of patients in all groups. Patients of the control group suffered from these diseases somewhat less frequently. Children's infectious diseases, such as chickenpox, measles, mumps, rubella, more often occurred in the anamnesis in women of groups 1 and 2 (62.7 ± 5.6 and 61.7 ± 7.1%, respectively), which is significantly more frequent than in the control group (19.1 ± 8.6%, p <0.01) and in women of group 3 with uterine myoma (13.9% ± 5.3, p <0.01).

Of interest is the frequency of previous hepatitis of various forms (A, B or C) in patients. Hepatitis was more often observed in patients of all three groups 6, 3.5 and 8 times more often (p <0.001) compared with the control group (4.8%). However, the highest incidence of hepatitis was observed in patients of group 3 with myoma (39.9 ± 7.5%), which is 2.3 times more often than in patients of group 2 with adenomyosis (17.0 ± 5.5%, p < 0.05). This is confirmed by the literature data on the relationship between the development of fibroids and liver pathology.

Some patients underwent appendectomy in childhood and adolescence. The frequency of this surgical intervention in the group with the combined form and in the groups with isolated pathologies was almost the same. Thus, patients of group 2 with adenomyosis underwent appendectomy more often - 19.1 ± 5.7% compared with group 3 of patients with myoma (16.3 ± 5.6% of cases). In patients with a combined form of fibroids and adenomyosis, surgery was performed in 18.7 ± 4.5% of cases.

Of somatic diseases, functional disorders of the nervous system, such as neuroses, depressive conditions, asthenoneurotic reactions, deserve great attention. So, every second patient with a combination of uterine fibroids and adenomyosis suffered from one or another pathology of the nervous system. Every third patient in groups 2 (36.2 ± 7.0%) and 3 groups (44.2 ± 7.6%) had functional disorders of the nervous system.

The second place is occupied by endocrine disorders (diffuse goiter, diabetes mellitus), of which the main part is occupied by diffuse goiter of varying degrees, which can be justified by the endemic iodine deficiency zone of the country. Most of all, endocrine disorders were detected in group 1 - 46.7 ± 5.8%, the frequency was almost 3.3 times higher than the data in the control group (14.3 ± 7.6%). In groups with isolated forms, the frequency of endocrine disorders was also significantly high (in group 2, 31.9 ± 6.9%, in group 3, 41.9 ± 7.5%, p <0.01).

Chronic anemia of moderate degree, which is more often a complication of the underlying pathology, is much more often (p <0.001) detected in patients of the main groups - in every third patient in groups 1 and 3 and in every 4 patient in group 2. In women in the control group, this pathology has not been identified.

In fourth place among somatic diseases is the pathology of the cardiovascular system (ischemic heart disease, angina pectoris, hypertension, hypotension, varicose veins of the lower extremities). In patients with a combined form of uterine fibroids and adenomyosis, cardiovascular diseases were detected 1.8 times more often than in patients with adenomyosis and 1.4 times more often than in patients with uterine fibroids. So, in group 1 in 34.7 ± 5.5% (p <0.001), in group 2 in 19.1 ± 5.7% (p <0.01) and in group 3 in 25.6 ± 6.7% (p <0.01) of the patients were diagnosed with similar diseases.

Diseases of the gastrointestinal tract (chronic gastritis, gastric ulcer and duodenal ulcer, chronic enterocolitis) were also detected in some patients of all main groups. Thus, 30.7 ± 5.3% of patients in group 1 (p <0.001), 21.3 ± 5.9% in group 2 (p <0.01) and 11.6 ± 4.9% in group 3 (p <0, 05) suffered from certain gastrointestinal diseases, i.e. these diseases were observed more often in patients with a combined form of fibroids and adenomyosis and only adenomyosis, compared with patients with fibroids.

Consequently, all patients of the examined groups had somatic health disorders, diseases of an infectious and inflammatory nature, endocrinopathy, anemia. However, the incidence of these diseases was higher in group 1 in patients with the combined form of myoma and adenomyosis.

Analysis of the reproductive history of the examined patients showed that in all three main groups the total number of pregnancies was high. The number of pregnancies among fertile women in one patient ranged from 1 to 14, on average there are 3.1 pregnancies per patient in the control group, and 1.5 - 1.7 times more in groups 1, 2 and 3 (Table 1).

However, more pregnancies ended in childbirth in the control group, which is 1.7 times more often compared with groups 1.2 (p <0.001, respectively) and 1.3 times more often than in group 3 of patients with uterine myoma. In these groups, the frequency of all types of reproductive losses (49.5 - 43.7 - 32%, respectively, p <0.001; p <0.01) was significantly higher than in the control group 12.7%. Induced abortions, spontaneous miscarriages, or termination of pregnancy due to a missed pregnancy often ended in curettage of the uterine cavity, which probably contributed to the development of adenomyosis (group 2) or a combined form of fibroids and adenomyosis (group 1).

Table 1: The nature of the reproductive function of the examined patients

Pregnancy outcomes	Control group, n= 21		Group #1, n= 75		Group #2, n=47		Group #3, n= 43	
	PLT	%	PLT	%	PLT	%	PLT	%
Childbirth	55	87,3±7,3	149	50,5±5,8 p<0,001	108	56,3±7,2 p<0,01	132	68±7,1 p>0,05
Induced abortion	7	11,1±6,9	111	37,6±5,6* p<0,001	63	32,8±6,8* p<0,001	52	26,4±6,7* p<0,01
Spontaneous miscarriages	1	1,6±2,7	21	7,1±2,9* P<0,05	14	7,3±3,8* t=1,92 p>0,05	9	4,6±3,2* t=1,43 p>0,05
Non-developing pregnancy	-	-	12	4,1±2,3 p>0,05	5	2,6±2,3	3	1,5±1,8
Ectopic pregnancy	-	-	2	0,7±0,9	2	1,0±1,4	1	0,5±1,1
Total pregnancies	63	100	295	100	192	100	197	100
Infertility patients	-		15	20±4,1 P<0,01	10	21,3±5,9 P<0,01	6	13,9±5,3 P<0,05
Pregnancies per patient	3,1		4,9		5,2		5,3	
Childbirth per 1 patient	2,6		2,5		2,9		3,6	

*Note: * - differences are significant in comparison with the control group.*

There was no difference between the groups in the frequency of ectopic pregnancy. One of the main complaints in patients of reproductive age with uterine myoma and adenomyosis is infertility. The duration of infertility in the surveyed women ranged from 2 years to 17 years.

In the main groups, some women had infertility, which was also a complication of adenomyosis and a combination of adenomyosis and fibroids. In the group with the combined form of uterine fibroids and adenomyosis, infertility was revealed in 15 patients. Compared to the second group, in the first group, primary infertility was revealed more - in 11 patients (73.3%), secondary infertility in 6 (40%) patients. Among them, 2 patients had both primary and secondary infertility. In group 2, out of 11 infertile patients, one third had primary infertility, 63.6% had secondary infertility. Among them, one patient had a history of both primary and secondary infertility. Somewhat less frequently (1.4-1.5 times) infertility was detected in group 3 of patients with myoma. As in group 2 with adenomyosis, in women with uterine myoma, secondary infertility (66.7%) prevailed over primary (33.3 %%). In the control group, this pathology was not revealed.

Clinical manifestations of the disease, in addition to infertility, in the examined patients were: in group 1 menstrual irregularities - in 52 - 69.3%, algomenorrhea - in 49 - 65.3%, dyspaniuria - in 33 - 44.0%; in group 2 - algomenorrhea - in 31 - 65.9%, menstrual irregularities - in 20 - 42.6%, dyspaniuria - in 14 - 29.8%. In group 3, 7 (16.3%) patients had myoma asymptomatic and was detected accidentally by ultrasound, and 36 (83.7%) patients had complaints of hypermenorrhea - in 23 - 63.9%, algomenorrhea - in 7 - 19.4%, dysfunction of neighboring organs - in 2 - 5.6% of women.

To establish the diagnosis, all patients underwent a sonographic study of the small pelvis, and in 1/3 of the patients, doppler studies of the blood flow of the vessels of myomatous nodes and foci of adenomyosis were also carried out. During ultrasound examination, the presence of myomatous nodes in the uterus was assessed, indicating their size, number, topography and type, as well as the presence of adenomyotic foci. Doppler analysis determined the presence of a vessel feeding the node, blood flow velocity and resistance index (RI) around and inside myomatous and adenomyotic nodes, as well as in the uterine arteries with diffuse adenomyosis. This made it possible to differentiate uterine fibroids from adenomyosis, to establish the type of node (simple or proliferating).

Color Doppler scanning revealed high vascular resistance of the uterine artery and its branches to the ovary. Especially with grade 2 and 3 adenomyosis, an increase in the resistance of blood flow in the uterine arteries from 0.85 to 0.93 was revealed. RI in the radial arteries was 0.67-0.78.

In 64% of patients of group 1, a combination of proliferating uterine fibroids with various forms of adenomyosis was revealed, of which a combination with diffuse adenomyosis - in 48%, with focal adenomyosis - in 4%, with nodular adenomyosis - in 4%, also in 8% of patients 1 -group revealed a combination of proliferating myoma with diffuse-nodular form of adenomyosis. In 36% of patients in group 1, a combination of a simple

type of myomatous nodes with various forms of adenomyosis was revealed, of which with diffuse adenomyosis - in 28%, with a focal form - in 4%, with a diffuse-nodular form of adenomyosis - in 4% of patients. In proliferating myoma, the vessel supplying the node and many small vessels around the node were clearly defined, the resistance index (RI) determined in such vessels ranged from 0.40 to 0.53. With simple myoma of small size up to 2 cm in diameter, blood flow was not determined inside the node, and large vessels feeding the node were not detected. RI was higher (from 0.60 to 0.82), which indicated his low blood supply. Avascular nodes were often identified.

In group 2, patients with adenomyosis were found to have diffuse adenomyosis in 26 - 55.3%, focal adenomyosis in 14 - 29.8%, in 5 - 10.6% of nodular adenomyosis and in 2 - 4.3% of diffuse-nodular adenomyosis. In this case, the diameter of the foci ranged from 2 to 7.2 mm. The blood flow in the uterine arteries in diffuse adenomyosis was reduced compared with focal adenomyosis (RI 0.78-0.86).

In group 3, patients with myoma in 67.4% of cases revealed a proliferating type of nodes, and in 32.6% - a simple type. RI for proliferating nodes ranged from 0.40 to 0.51, and for simple type of nodes, RI was within 0.56-0.70.

Table 2: The quality of blood flow in the myomatous nodes of the uterus and / or with adenomyosis

1-group (combined pathology)	RI indicators	
	RIaround the node	RI inside the node
Simple fibroid	0,83±0,04	0,79±0,06
Proliferating fibroids	0,53±0,03	0,49±0,02
In combination with:		
Diffuse adenomyosis	Right Uterine Artery	Left Uterine Artery
IR	0,77±0,02	0,75±0,02
FROM TO	4,14	3,28
2-group		
Diffuse adenomyosis	Right Uterine Artery	Left Uterine Artery
1-degree	0,74±0,01	0,71±0,003
2-3 degrees	0,89±0,02	0,86±0,01
3-group		
	RIaround the node	RI inside the node
Simple myoma	0,76±0,02	0,65±0,03
Proliferating fibroids	0,54±0,01	0,49±0,02

Ultrasound examinations of the uterus revealed the presence of hyperplastic endometrium mainly in patients with a combined form of uterine myoma and adenomyosis (group 1) - in 29 - 38.7%, and with uterine myoma (group 3) - in 15 - 34.9%. Among them, 81.8% of patients had endometrial hyperplasia, and 18.2% of patients had an endometrial polyp.

The treatment was carried out depending on the revealed pathology. In isolated fibroids, ulipristal acetate 5 mg (UPA) was prescribed for 3 months for at least 2 courses of 3 months with a two-month break, in adenomyosis - dienogest 2 mg for 6 months continuously. With the combined form of fibroids and adenomyosis, treatment was started with dienogest for 6 months continuously, then UPA was prescribed for 3 months. The results of treatment within 6-8 months showed that in the majority of patients (112 patients - 81.2%), the cycle normalized, the pain disappeared. A quarter of patients became pregnant after the end of treatment.

Among 30 (18.2%) patients of late reproductive age, hysterectomy was performed for various reasons (in 18 (24%) patients in group 1, in 5 (10.6%) patients in group 2, and in 7 (16.3 %) of patients of group 3). The most common cause of hysterectomy in them was bleeding against the background of submucous uterine fibroids or a combination of multinodular fibroids with adenomyosis - 25 - 83.3%. Algomenorrhea, a symptom of dysfunction of adjacent organs, and rapid growth of nodes in only 2% of patients were indications for hysterectomy. In 3% of patients of reproductive age, myomectomy was performed for infertility after a course of UPA.

Thus, the high frequency of the combination of uterine fibroids and adenomyosis has an extremely negative effect on reproductive and menstrual functions, reduces the quality of life of patients, and also has an increased risk of developing cancer. To select a method of treatment and the selection of drugs, it is important to clarify the clinical and morphological variant of myoma (simple or proliferating node), the features and nature of adenomyosis (focal or diffuse form), the severity of the vascularization process, as well as the presence of hyperplastic changes in the endometrium. This allows you to correctly choose an effective course of treatment, especially with a combined form of the disease.

IV. Conclusions

1. Patients with concomitant pathology in childhood are more exposed to chronic inflammatory diseases, they are more exposed to somatic diseases, often develop functional disorders of the

nervous system, which leads to a decrease in the quality of life of a woman.

2. Combined forms of uterine fibroids and adenomyosis have a more pronounced clinical picture, lead to reproductive losses, are often complicated by infertility and require long-term treatment.
3. Comprehensive examination and treatment of these diseases allows women to restore menstrual and reproductive functions in 25% of cases during the first year after treatment. Clinical recovery was noted in 87% of women who had any complaints.

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Fellows/Associates of Medical Research Council

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19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.

20. Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

22. Report concluded results: Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

23. Upon conclusion: Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium though which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

Informal Guidelines of Research Paper Writing

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

The introduction: This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.

Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

Introduction:

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.

The following approach can create a valuable beginning:

- Explain the value (significance) of the study.
- Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
- Briefly explain the study's tentative purpose and how it meets the declared objectives.

Approach:

Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

Procedures (methods and materials):

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.

Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

Content:

- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- Present a background, such as by describing the question that was addressed by creation of an exacting study.
- Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

What to stay away from:

- Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- Do not include raw data or intermediate calculations in a research manuscript.
- Do not present similar data more than once.
- A manuscript should complement any figures or tables, not duplicate information.
- Never confuse figures with tables—there is a difference.

Approach:

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

Figures and tables:

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

Discussion:

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an argument should be.

Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact, you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved the prospect, and let it drop at that. Make a decision as to whether each premise is supported or discarded or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."

Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- Give details of all of your remarks as much as possible, focusing on mechanisms.
- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- Recommendations for detailed papers will offer supplementary suggestions.

Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

The Administration Rules

Administration Rules to Be Strictly Followed before Submitting Your Research Paper to Global Journals Inc.

Please read the following rules and regulations carefully before submitting your research paper to Global Journals Inc. to avoid rejection.

Segment draft and final research paper: You have to strictly follow the template of a research paper, failing which your paper may get rejected. You are expected to write each part of the paper wholly on your own. The peer reviewers need to identify your own perspective of the concepts in your own terms. Please do not extract straight from any other source, and do not rephrase someone else's analysis. Do not allow anyone else to proofread your manuscript.

Written material: You may discuss this with your guides and key sources. Do not copy anyone else's paper, even if this is only imitation, otherwise it will be rejected on the grounds of plagiarism, which is illegal. Various methods to avoid plagiarism are strictly applied by us to every paper, and, if found guilty, you may be blacklisted, which could affect your career adversely. To guard yourself and others from possible illegal use, please do not permit anyone to use or even read your paper and file.

Criterion for Grading a Research Paper (Compilation) by Global Journals

Please note that following table is only a Grading of "Paper Compilation" and not on "Performed/Stated Research" whose grading solely depends on Individual Assigned Peer Reviewer and Editorial Board Member. These can be available only on request and after decision of Paper. This report will be the property of Global Journals.

Topics	Grades		
	A-B	**C-D**	**E-F**
Abstract	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
Introduction	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
Methods and Procedures	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
Result	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
Discussion	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
References	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring

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