SURAT KETERANGAN

Yang bertanda tangan di bawah ini:

Nama Pembimbing Klinik : MEILIANA, A.Md.Keb

Instansi : Puskesmas Tanjungsari Gunungkidul

Dengan ini menerangkan bahwa:

Nama Mahasiswa : MUTIA RAHMAWATI

NIM : P07124522038

Prodi : Pendidikan Profesi Bidan

Jurusan : Kebidanan Poltekkes Kemenkes Yogyakarta

Telah selesai melakukan asuhan kebidanan berkesinambungan dalam rangka praktik kebidanan holistik Continuity of Care (COC)

Asuhan dilaksanakan pada tanggal 13 Desember 2022 sampai dengan 29 Januari 2023

Judul asuhan: "ASUHAN KEBIDANAN PADA NY EW USIA 40 TAHUN G4P3A0 DENGAN KEHAMILAN RESIKO TINGGI DI PUSKESMAS TANJUNGSARI GUNUNGKIDUL"

Demikian surat keterangan ini dibuat dengan sesungguhnya untuk dipergunakan sebagaimana mestinya.

Gunungkidul, Mei 2023

Bidan Pembimbing Klinik

MEILIANA, A.Md.Keb

INFORMED CONSENT (SURAT PERSETUJUAN)

Yang bertanda tangan di bawah ini:

Nama : Endang Wijayanti
Tempat/Tanggal Lahir : Boyolali, 12-6-1982
Alamat : Gaduhan Hargosari Tanjungsari

Bersama ini menyatakan kesediaan sebagai subjek dalam praktik Continuity of Care (COC) pada mahasiswa Prodi Pendidikan Profesi Bidan T.A. 2022/2023. Saya telah menerima penjelasan sebagai berikut:

1. Setiap tindakan yang dipilih bertujuan untuk memberikan asuhan kebidanan dalam rangka meningkatkan dan mempertahankan kesehatan fisik, mental ibu dan bayi. Namun demikian, setiap tindakan mempunyai risiko, baik yang telah diduga maupun yang tidak diduga sebelumnya.
2. Pemberi asuhan telah menjelaskan bahwa ia akan berusaha sebaik mungkin untuk melakukan asuhan kebidanan dan menghindarkan kemungkinan terjadinya risiko agar diperoleh hasil yang optimal.
3. Semua penjelasan tersebut di atas sudah saya pahami dan dijelaskan dengan kalimat yang jelas, sehingga saya mengerti arti asuhan dan tindakan yang diberikan kepada saya. Dengan demikian terdapat kesepahaman antara pasien dan pemberi asuhan untuk mencegah timbulnya masalah hukum di kemudian hari.

Demikian surat persetujuan ini saya buat tanpa paksaan dari pihak manapun dan agar dipergunakan sebagaimana mestinya.

Yogyakarta, 13-12-2023

Mahasiswa	Klien
Mutia Rahmawati	Endang Wijayanti

LAMPIRAN

ASUHAN KEBIDANAN PADA IBU HAMIL

Ny E Usia 40 Tahun G4P3Ab0Ah3 Usia Kehamilan 36^{+2} Minggu dengan Plasenta Previa dan Anemia Ringan di Puskesmas Tanjungsari

NO MR	:		
IDENTITAS PASIEN	:	IBU	SUAMI
NAMA	:	Ny E	Tn B
TANGGAL LAHIR/UMUR	:	20/06/1982 (40 th)	41 th
PENDIDIKAN	:	S1	SMA
PEKERJAAN	:	Ibu Rumah Tangga	Honorer
ALAMAT	:	Gaduhan, Hargosari, Tanjungsari	
N0 HP	:	08812785747	
Pengkajian : 13-12-2022		Jam 09.00 WIB	

S : Berdasarkan hasil pengkajian di rumah pasien saat kunjungan rumah pada hari Selasa, 13 Desember 2022 diperoleh data Ny E Usia 40 tahun, pernah melahirkan normal 3 x, belum pernah keguguran, jumlah anak hidup 3 orang, anak terkecil 4 tahun. Ibu mengatakan riwayat menstruasi pertama kali usia 13 tahun lama menstruasi 7 hari dan tidak ada keluhan, riwayat pernikahan ibu menikah pada usia 25 tahun dan ini merupakan pernikahan pertama ibu. Sejak melahirkan anak pertama ibu belum pernah menggunakan alat kontrasepsi. riwayat kehamilan sekarang menstruasi terakhir (HPHT) 08-04-2022 dam HPL 15-01-2023, dan telah melakukan pemeriksaan kehamilan sebelumnya di PMB sejak usia kehamilan 8 minggu sebanyak 4 x, ANC terpadu dipuskesmas 1 x, dan USG dengan dokter obsgun 2 x. Menurut keterangan dokter dari hasil USG posisi plasenta berada di jalan lahir dan menutupi jalan lahir secara total. Selama kehamilan ibu tidak pernah mengalami perdarahan per vagina. Pola pemenuhan kebutuhan sehari-hari ibu mengatakan tidak ada permasalahan minum 6-7 gelas sehari banyaknya 1300 ml, makan 2x

sehari dan macamnya bervariasi hanya saja ibu mual saat melihat nasi. Pola pemenuhan lainnya dalam batas normal tidak ada perubahan sebelum dan saat hamil. Riwayat kehamilan lalu ibu mengatakan ini kehamilan pertama. Pengkajian pada riwayat psikologis ibu merasa cemas dengan kehamilannya, ibu tidak memiliki riwayat penyakit menahun maupun menular.

O : Ku: baik, TD: 112/80 mmHg, N: 78 x/m, R: 20 x/m, S: 36,5°C. TB: 153,5 cm, sebelum hamil BB: 55 kg, periksa sebelumnya BB:63 kg, BB sekarang 63 kg, IMT: 25,89 kg/$m^{2,}$ LILA: 26 cm . Mata simetris, konjungtiva tidak pucat, mulut tidak sariawan, leher tidak ada pembengkakan kelenjar limfe atau vena jugularis, tidak ada pembesaran kelenjar tiroid, payudara simetris, puting menonjol, tidak ada benjolan. Abdomen: tfu 30 cm, Leopold I teraba bokong, Leopold II punggungkanan, Leopold III teraba kepala, Leopold IV Divergen/ belummasuk PAP, Djj 144x/m.

Pemeriksaan penunjang pemeriksaan sebulan yang lalu: HB 10,2 gr%,

A : Seorang ibu Ny.E umur 40 tahun G4P3Ab0Ah3 usia kehamilan 36^{+2} minggu dengan plasenta previa dan anemia ringan, masalah kecemasan dan ketidaknyamanan dengan kebutuhan KIE tentang kondisi yang dihadapi, faktor kemungkinan penyebab dan cara mengatasi, potensial perdarahan ante partum yang bisa menyebabkan kematian janin dalam kandungan , antisipasi tindakan segera tentang manajemen tatalaksana anemia dan melakukan rujukan ke Fasilitas Kesehatan Tk II/RS untuk perencanaan persalinan Secsio Cesaria pada usia kehamilan cukup bulan

P : 13/12/2022 jam 09.10 WIB

1. Memberitahu ibu hasil pemeriksaan bahwa ibu sekarang dalam kondisi hamil 36^{+2} minggu, masuk kehamilan trimester 3 dengan masalah plasenta previa dan anemia ringan, resiko yang mungkin terjadi dan cara mengatasinya.
2. KIE manajemen plasenta previa
   - Istirahat baring

- Menghindari berhubungan suami istri
- Tidak melakukan aktifitas yang dapat menimbulkan kontraksi rahim

3. Memberikan tablet tambah darah 1x1 (10tablet), asam folat 1 x 1 (10 tablet), Kalsium laktat 1x1 (10 tablet) dan cara meminum obat yang benar.
4. Memotivasi suami dan keluarga untuk memberikan dukungan kepada ibu agar dapat melewati kehamilannya dan mengurangi tingkat kecemasan ibu,dengan memberikan makanan yang bergizi seimbang, membantu pekerjaan rumah dan merawat anak-anaknya.
5. Memotivasi ibu untuk membaca dan memahami semua yang ada dibuku kia dan menjelaskan manfaat buku KIA.
6. Menjelaskan tentang KB pasca salin dan memotivasi ibu untuk berKB segera setelah melahirkan
7. Menganjurkan ibu periksa ke dokter SpOG 1 minggu lagi atau sesuai jadwal untuk perencanaan persalinan di RS.
8. Memotivasi suami dan keluarga untuk mempersiapkan kebutuhan untuk persalinan antara lain transportasi, dana, rujukan, jaminan kesehatan, perlengkapan ibu dan bayi dan siaga membawa ibu ke RS jika terjadi perdarahan.

Pengkajian : 28-12-2022 Jam 11.00 WIB

S : Pada kunjungan rumah yang kedua ibu mengeluh sering kenceng-kenceng,perut sering tegang. Ibu mengatakan tidak betah harus tiduran terus menerus di tempat tidur. Ibu tetap melakukan pekerjaan rumah rutin seperti biasa seperti membersihkan rumah, mencuci, belanja ke warung dan mengantar anaknya sekolah. suami bekerja dari pagi sampai sore hari, dan dirumah ibu mertua juga bekerja di sawah. ibu merasa sehat dan tidak ada keluhan pada kehamilannya.

O : Ku: baik, TD: 120/78 mmHg, N: 74 x/m, R: 20 x/m, S: 36,8°C.

A : orang ibu Ny.E umur 40 tahun G4P3Ab0Ah3 usia kehamilan 37^{+3} minggu dengan plasenta previa dan anemia ringan, masalah kecemasan dan ketidaknyamanan dengan kebutuhan KIE tentang kondisi yang dihadapi, faktor kemungkinan penyebab dan cara mengatasi, potensial perdarahan ante partum yang bisa menyebabkan kematian janin dalam kandungan , antisipasi tindakan segera tentang manajemen tatalaksana anemia dan melakukan rujukan ke Fasilitas Kesehatan Tk II/RS untuk perencanaan persalinan Secsio Cesaria pada usia kehamilan cukup bulan

P : 28/12/2022 jam 09.10 WIB

1. Memberitahu ibu hasil pemeriksaan bahwa ibu sekarang dalam kondisi hamil 36^{+2} minggu, masuk kehamilan trimester 3 dengan masalah plasenta previa dan anemia ringan, resiko yang mungkin terjadi dan cara mengatasinya.
2. KIE manajemen plasenta previa
   - Istirahat baring
   - Menghindari berhubungan suami istri
   - Tidak melakukan aktifitas yang dapat menimbulkan kontraksi rahim
3. Memberikan tablet tambah darah 1x1 (10tablet), asam folat 1 x 1 (10 tablet), Kalsium laktat 1x1 (10 tablet) dan cara meminum obat yang benar.
4. Memotivasi suami dan keluarga untuk memberikan dukungan kepada

ibu agar dapat melewati kehamilannya dan mengurangi tingkat kecemasan ibu,dengan memberikan makanan yang bergizi seimbang, membantu pekerjaan rumah dan merawat anak-anaknya.

5. Memotivasi ibu untuk membaca dan memahami semua yang ada dibuku kia dan menjelaskan manfaat buku KIA.
6. Menjelaskan tentang KB pasca salin dan memotivasi ibu untuk berKB segera setelah melahirkan
7. Menganjurkan ibu periksa ke dokter SpOG 1 minggu lagi atau sesuai jadwal untuk perencanaan persalinan di RS.
8. Memotivasi suami dan keluarga untuk mempersiapkan kebutuhan untuk persalinan antara lain transportasi, dana, rujukan, jaminan kesehatan, perlengkapan ibu dan bayi dan siaga membawa ibu ke RS jika terjadi perdarahan.

ASUHAN KEBIDANAN PADA BAYI BARU LAHIR

By.Ny E Usia 1 hari dengan Riwayat Persalinan Sectio Caesaria atas Indikasi Plasenta Previa Totalis dengan Post Perawatan Asfiksia di Puskesmas Tanjungsari

NO MR	:		
IDENTITAS PASIEN	:	IBU	SUAMI
NAMA	:	Ny E	Tn B
TANGGAL LAHIR/UMUR	:	20/06/1982 (40 th)	41 th
PENDIDIKAN	:	S1	SMA
PEKERJAAN	:	Ibu Rumah Tangga	Honorer
ALAMAT	:	Gaduhan, Hargosari, Tanjungsari	
No HP	:	08812785747	
Pengkajian : 31-12-2022		Jam 10.00 WIB	

S : Ibu mengatakan bayinya sudah lahir di RS Pelita Husada pada tanggal 29 Desember 2022 jam 19.15 WIB secara Sectio Caerasria. Jenis Kelamin Laki-laki dengan berat lahir 2800 gram panjang 49cm. Ibu mengatakan bayinya lahir tidak langsung menangis dan nafasnya megap-megap. Ibu menyampaikan jika bayinya akan dirujuk ke RS Sarjito karena diduga menderita kelainan jantung bawaan. Dari RS Pelita husada sedang berusaha mencarikan tempat rujukan. Saat lahir bayinya tidak di IMD.

O : Hasil pengaamatan saat kontak denganibu dan bayi di RS Pelita husada tanpak bayi di dalam inkubator terpasang oksigen dan NGT. Bayi tampak lemah, menangis merintih dan nafas tersengal-sengal dan tampak retraksi dinding dada. Bayi diberi minum melalui selang NGT.

A : By Ny EW usia 1 hari riwayat persalinan SC dengan asfiksia

P Memberikan support kepada ibu untuk tetap tenang dan mendoakan bayinya agar segera mendapat pertolongan dan tempat rujukan

Menanyakan kepada bidan jaga di RS Pelita Husada untuk alternatif RS rujukan selain RSUP dr Sarjito. Bidan jaga mengusahakan untuk merujuk ke RS PKU Yogyakarta setelah berkonsultasi dengan dokter Spesialis anak.

Memotivasi ibu untuk melakukan mobilisasi secara dini agar dapat merawat dirinya saat mendampingi bayinya ke RS Rujukan.

Pengkajian : 10-1-2023 : Jam 10.00 WIB

S : Ibu mengatakan bayinya sudah pulang dari RS PKU Yogyakarta pada tanggal 8 Januari setelah dirawat selama 8 hari. Ibu mengatakan bayinya BAK sering, warna kuning jernih dan BAB sehari 4-5 kali, warna kuning keemasan. Saat pulang dari RS PKU Yogyakarta BB bayi 3000 gram. Berdasarkan resume medis dari RS bayi mengalami respirastory distress sindrom. Dari hasil pengamatan keadaan bayi tampak bugar, warna kulit kemerahan, bayi aktif dan menyusu dengan lahap

O : Hasil pengukuran tanda vital Suhu 36,8C, Respirasi 40x/m, Heart Rate 146x/m, bentuk kepala mesochepal, tidak ada caput succedanium, tidak ada cephalhematoma, mata simetris, sklera putih, dada tidak tampak tarikan dinding dada, tidak ada wheezing, perut tidak kembung, bising usus normal, kulit tidak keriput, tidak ikterik, tidak ada kelainan bawaan.

A : By Ny EW usia 12 hari riwayat persalinan SC post opname dengan asfiksia

P : memberikan KIE dan mengajarkan ibu tentang teknik menyusui,

ASI eksklusif, dan memotivasi ibu untuk memberikan ASI secara *on demand,* memberikan KIE tanda-tanda bahaya pada bayi baru lahir seperti demam, kejang, memuntahkan semuanya, tidak mau menyusu, bayi kuning, sesak nafas/nafas cepat dan lain-lain. Menganjurkan untuk kontrol sesuai jadwal dari RS atau segera membawa bayi ke RS jika ada tanda bahaya.

ASUHAN KEBIDANAN PADA IBU NIFAS

Ny E Usia 40 Tahun P4Ab0Ah4 dengan Riwayat Sectio Caesaria Hari ke 1 di Puskesmas Tanjungsari

NO MR	:		
IDENTITAS PASIEN	:	IBU	SUAMI
NAMA	:	Ny E	Tn B
TANGGAL LAHIR/UMUR	:	20/06/1982 (40 th)	41 th
PENDIDIKAN	:	S1	SMA
PEKERJAAN	:	Ibu Rumah Tangga	Honorer
ALAMAT	:	Gaduhan, Hargosari, Tanjungsari	
No HP	:	08812785747	
Pengkajian : 31-12-2022		Jam 10.00 WIB	

S : Ibu mengatakan sudah melahirkan tanggal 29 Desember 2022 jam19.15 secara sectio caesaria. Saat ini keluhan luka masih terasa sakit. Keluar darah sedikit seperti haid, warna merah kehitaman. Ganti pembalut tiap 4 jam sekali. Ibu mengatkan khawatir dengan kondisi bayinya karena menurut dokter ada gangguan pada jantung dan paru-parunya. Ibu sudah makan sedikit-sedikit, belum beranijalan ke kamar mandi, BAK menggunakan pispot. Ibu sudah latihan duduk. Ibu mengatakan belum bisa tidur pulas karena khawatir dengan bayinya dan anak ketiganya selalu rewel.

O : Dari hasil pengamatan kondisi ibu stabil, sudah bisa duduk sendiri. kesadaran composmentis, TD 110/78mmHg, Suhu 36,8 C, Nadi 90x/m, TFU setinggi pusat, tidakada perdarahan,lokhea rubra.

A : Ny EW usia 40 tahun P4A0Ah4 dengan persalinan Sectio Caesaria atas indikasi Plasenta Previa Totalis. Diagnosa potensial terjadinya perdarahan post partum. Masalah yang timbul pasca operasi adalah nyeri luka operasi dan rasa cemasakan keadaan bayinya

P : Memberikan support pada ibu agar tetaptenang meghadapi masalah pada bayinya dan mendoakan agar masalah segera dapat teratasi.

Memotivasi ibu untuk makan dengan teratur dan bergizi agar memiliki

kekuatan untuk mendampingi bayinya saat dirujuk ke RS rujukan.
Memotivasi ibu untuk latihan turun dari tempat tidur sesuai anjuran dokter agar pemulihan pasca operasi menjadi lebih cepat.
Memotivasi ibu untuk istirahat dan meminta anak keduanya untuk menjaga adiknya di luar ruangan agar tidak mengganggu istirahat serta menyerahkan penjagaan bayinya kepada petugas jaga di RS.

Pengkajian tanggal 6 Januari 2023 kontak melalui chat whatsap

S : Ibu mengabarkan kondisi bayinya membaik dan menurut dokter tidak ada kelainan jantung. Kondisi ibu baik tidak ada keluhan hanya susah tidur karena menghawatirkan anak ketiganya dirumah. Perdarahan sedikit dan keluar darah merah kehitaman. Luka jahitan tidak sakit dan 2 hari sebelumnya sudah diganti verbannya oleh bidan di RS. Ibu makan dari diet yang diberikan oleh RS dan selalu dihabiskan.

O : Tidak dilakukan pengkajian

A : Ny EW, usia 40 tahun post SC hari ke 8 berdasarkan data subyektif dalam kondisi normal

P : Memberikan KIE temtang pemenuhan kebutuhan istirahat, nutrisi dan perawatan luka agar penyembuhan lebih cepat
Memotivasi agar tidak khawatir keluarganya di rumah sudah bisa diatasi karena banyaktetangga dan keluarga yang membantu merawat anaknya.
Memberikan support kepada ibu agar tetap semangat untuk kesembuhan bayinya

Pengkajian tanggal 10 Januari 2023 jam 13.00WIB

S : Ibu mengatakan luka jahitan operasinya agak nyeri karena sudah 1 minggu perban belum diganti dan basah karena lupa tidak ditutup saat mandi. Ibu khawatir luka jahitannya terbuka dan infeksi, BAK dan BAB tak ada keluhan

O : Kondisi ibu stabil, kesadaran composmentis, TD 110/78mmHg, Suhu 36,8 C, Nadi 90x/m, tidak ada perdarahan, lokhea serosa, TFU 3 jari diatas simphisis. Dari hasil pemeriksaan luka jahitan tidak terdapat tanda infeksi seperti kemerahan, bengkak, nanah/pus, ataupun demam

A : Ny EW usia 40 tahun P4A0Ah4 dengan persalinan Sectio Caesaria atas indikasi Plasenta Previa Totalis. Diagnosa potensial terjadinya perdarahan post partum. Masalah yang timbul pasca operasi adalah nyeri luka operasi dan rasa cemasakan keadaan bayinya

P : memberikan KIE dan mengajarkan ibu tentang teknik menyusui, ASI eksklusif, dan memotivasi ibu untuk memberikan ASI secara *on demand*, memberikan KIE tanda-tanda bahaya pada bayi baru lahir seperti demam, kejang, memuntahkan semuanya, tidak mau menyusu, bayi kuning, sesak nafas/nafas cepat dan lain-lain. Menganjurkan untuk kontrol sesuai jadwal dari RS atau segera membawa bayi ke RS jika ada tanda bahaya.

Penatalaksanaan pada pertemuan ini adalah memberitahu ibu bahwa kondisinya baik tetapi luka operasinya perlu perawatan, mengajarkan ibu teknik relaksasi napas dalam untuk mengurangi rasa nyeri, kemudian, KIE mengenai personal hygiene ibu nifas (membersihkan payudara dengan air hangat sebelum menyusui, cuci tangan dengan sabun sebelum dan sesudah kontak dengan bayi dan memegang kemaluan, menjaga kebersihan jalan lahir, memberikan KIE pada ibu

mengenai makanan ibu nifas tidak ada pantangan dan sebaiknya makan yang banyak mengandung karbohidrat, protein dan mineral. Selain itu juga minum air putih yang banyak dan juga mengingatkan ibu untuk minum obat dengan teratur, melakukan perawatanluka dengan mengganti perban yang basah dengan yang kering dan steril,Menganjurkan ibu untuk konsumsi putih telur atau ikan agar luka cepssembuh. Menganjurkan ibu untuk cukup istirahat agar ibu memiliki tenaga untuk menyusui dan merawat bayinya, menganjurkan ibu untuk kontrol ke RS jika luka masih terasa nyeri atau keluar nanah.

Pengkajian tanggal 29 Januari 2023 di PMB Mutia

S : Ibu mengatakan ingin mengimunisasikan bayinya karena sudah umur 1 bulan dan belum imunisasi BCG. Bayinya sudah tidak ada keluhan dantidak kontrol lagi ke RS, sesuai rekomendasi dokter bayinya boleh diimunisasi. Ibu tidak ada keluhan dan luka jahitan SC sudah kering dan tidak sakit. Sudah tidak keluar darah dan ada sedikit keluar lendir berwarna bening dan tidak gatal.ibu sudah bisa merawat bayinya sendiri seperti memandikan dan bisa melakukan pekerjaan rumah yang ringan dengan dibantu anak keduanya saat pulang sekolah.

O : Kondisi ibu stabil, kesadaran composmentis, TD 120/78mmHg, Suhu 36,6 C, Nadi 78x/m, tidak ada perdarahan, lokhea serosa, TFU tak teraba. Dari hasil pemeriksaan luka jahitan tidak terdapat tanda infeksi seperti kemerahan, bengkak, nanah/pus, ataupun demam.

A : Ny EW usia 40 tahun P4A0Ah4 dengan masa nifas post SC hari ke 30 dengan keadaan normal

P : memberikan KIE dan mengajarkan ibu tentang teknik menyusui, ASI eksklusif, dan memotivasi ibu untuk memberikan ASI secara *on demand*, memberikan KIE tanda-

tanda bahaya pada bayi baru lahir seperti demam, kejang, memuntahkan semuanya, tidak mau menyusu, bayi kuning, sesak nafas/nafas cepat dan lain-lain. Menganjurkan untuk kontrol sesuai jadwal dari RS atau segera membawa bayi ke RS jika ada tanda bahaya.

Penatalaksanaan pada pertemuan ini adalah memberitahu ibu bahwa kondisinya baik tetapi luka operasinya perlu perawatan, mengajarkan ibu teknik relaksasi napas dalam untuk mengurangi rasa nyeri, kemudian, KIE mengenai personal hygiene ibu nifas (membersihkan payudara dengan air hangat sebelum menyusui, cuci tangan dengan sabun sebelum dan sesudah kontak dengan bayi dan memegang kemaluan, menjaga kebersihan jalan lahir, memberikan KIE pada ibu mengenai makanan ibu nifas tidak ada pantangan dan sebaiknya makan yang banyak mengandung karbohidrat, protein dan mineral. Selain itu juga minum air putih yang banyak dan juga mengingatkan ibu untuk minum obat dengan teratur, melakukan perawatan luka dengan mengganti perban yang basah dengan yang kering dan steril, Menganjurkan ibu untuk konsumsi putih telur atau ikan agar luka cepat sembuh. Menganjurkan ibu untuk cukup istirahat agar ibu memiliki tenaga untuk menyusui dan merawat bayinya, menganjurkan ibu untuk kontrol ke RS jika luka masih terasa nyeri atau keluar nanah.

ASUHAN KEBIDANAN PADA AKSEPTOR KB

Ny E Usia 40 Tahun P4Ab0Ah4 dengan Konseling KB IUD

NO MR	:		
IDENTITAS PASIEN	:	IBU	SUAMI
NAMA	:	Ny E	Tn B
TANGGAL LAHIR/UMUR	:	20/06/1982 (40 th)	41 th
PENDIDIKAN	:	S1	SMA
PEKERJAAN	:	Ibu Rumah Tangga	Honorer
ALAMAT	:	Gaduhan, Hargosari, Tanjungsari	
No HP	:	08812785747	
Pengkajian : 29-1-2023		Jam 12.00 WIB	

S : Ibu mengatakan keadaan bayinya sehat dan sudah tidak kontrol ke RS lagi. Bayinya menyusu kuat, BAK dan BAB tidak ada keluhan, ASI cukup, keadaan ibu sehat, luka operasi sudah kering dan sudah tidak di perban serta bisa mandi seperti biasa. Ibu mengatakan belum berfikir untuk menggunakan KB saat ini karena ingin fokus merawat bayinya. Sebelumnya ibu pernah menggunakan KB suntik 3 bulanan tetapi karena sering keluar darah flek dan lama sehingga KB dihentikan. Ibu mengatakan tidak menginginkan hamil lagi tetapi suami tidak mengijinkan untuk MOW atau steril.

Dapat disimpulkan bahwa ibu nifas hari ke 30 dengan kebutuhan konseling KB pasca salin. Oleh karena itu pelaksanaan untuk masalah tersebut adalah penggunaan KB. Suami mengatakan sepertinya akan memilih metode IUD. Menganjurkan ibu untuk datang ke PMB atau puskesmas sebelum masa nifas selesai atau sebelum 42 hari setelah melahirkan untuk diperiksa dan jika memenuhi syarat akan langsung dipasang IUD.

O : Pada pemeriksaan didapatkan hasil bahwa KU ibu baik, kesadaran compos mentis, TD: 110/80 mmHg, N: 86 kali/menit, R: 21 kali/menit, S 36,9 °C.

Secara umum pemeriksaan fisik dari kepala hingga kaki ibu dalam keadaan yang normal, dengan payudara membesar tak teraba pembengkakan, ada pengeluaran ASI, TFU tak teraba, , lochea alba.

A : Ny EW usia 40 tahun P4A0Ah4 dengan Riwayat Sectio Caesaria dengan konseling KB. Diagnosa potensial tidak ada

P : 29/1/2023 jam 09.10 WIB

memberitahu ibu bahwa kondisinya normal dan sehat, menjelaskan pada ibu mengenai tujuan penggunaan alat kontrasepsi yaitu untuk mengatur jarak kelahiran sehingga ibu tidak terlalu dekat jarak antar kehamilannya yang dapat berisiko terhadap kesehatan ibu dan bayi. Setelah masa nifas berakhir yaitu enam minggu kesuburan ibu dapat kembali. Sehingga sebelum ibu melakukan hubungan seksual dengan suami sebaiknya ibu berKB terlebih dahulu, kemudian menjelaskan pada ibu macam-macam jenis alat kontrasepsi, efektivitas, keuntungan dan kerugian, serta efek samping dari berbagai jenis alat kontrasepsi.

Melakukan penapisan kelayakan medis menggunakan aplikasi roda klop. Dari hasil penapisan tidak diperoleh masalah kesehatan ibu dan ibu bisa menggunakan semuajenis alat kontrasepsi. Berdasarkan kondisi ibu dianjurkan untuk menggunakan alat kontrasepsi jangka panjang.

Menganjurkan ibu untuk berdiskusi dengan suami tentang pemilihan alat kontrasepsi sesuaidengan kondisinya.

Ibu dan suami memilih menggunakan IUD setelah masa nifas selesai.

Evalusasi : ibu sudah dipasang IUD di Puskesmas pada tanggal 6 Februari 2023.

LAMPIRAN DOKUMENTASI ASUHAN

Kunjungan Rumah Ibu hamil pertama

Kunjungan Ibu bersalin di RS Pelita Husada

Kunjungan Bayi baru lahir Post opname

LAMPIRAN JURNAL

Hindawi
International Journal of Clinical Practice
Volume 2022, Article ID 7750598, 6 pages
https://doi.org/10.1155/2022/7750598

Research Article

Combined Efficacy of Balloon Occlusion and Uterine Artery Embolization on Coagulation Function in Patients with High-RiskPlacenta Previa during Cesarean Section

Xiaoli Xu and Xiayun Zhu

Department of Obstetrics and Gynecology, Gezhouba Central Hospital of Sinopharm, China Three Gorges University, Yichang, Hubei, China

Correspondence should be addressed to Xiayun Zhu; 23067719@qq.com

Received 6 December 2021; Revised 28 January 2022; Accepted 21 February 2022; Published 4 April 2022

Academic Editor: Federico Giorgio Ferrari

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Purpose. The present study was performed in order to investigate the conbined effect of balloon occlusion and uterine artery em- bolization on coagulation function in patients with high-risk placenta previa during cesarean section. *Methods*. There involved a total of 38 patients with high-risk placenta previa undergoing cesarean section in our hospital from August 2019 to January 2021. The patients enrolled were randomly divided into study group (19 cases, receiving balloon occlusion combined with uterine artery embolization) and control group (19 cases, receiving conventional cesarean section). The operation time, intraoperative blood loss, plasma injection volume and hospital stay of the two groups were recorded. Moreover, the postoperative coagulation function indexes, including thrombin time (TT), fibrinogen (FBI), activated partial thromboplastin time (APTT) and prothrombin time (PT), were monitored and compared. Neonatal Apgar score and postoperative complications of the two groups were regarded as parameters for comparison. *Results*. The intraoperative blood loss, plasma injection volume and hospital stay of the study group were significantly lower compared with the control group ($P < 0.05$), whereas the operation time of the

two groups was comparable ($P > 0.05$). Compared with the control group, the levels of TT, APTT and PT were lower while the level of FBI was higher in the study group ($P < 0.05$). The Apgar 1-min and 5-min scores of newborns were compared between the two groups ($P > 0.05$). However, the incidence of postoperative complications in the study group showed evidently lower outcomes compared with the control group ($P < 0.05$). *Conclusion*. The combined approach of balloon occlusion and uterine artery embolization offered potential for improving the coagulation function of patients with high-risk placenta previa during cesarean section. In addition, the approach reduced the amount of blood loss and plasma injection, shortened the length of hospital stay, which was believed available for wide clinical application.

1. Introduction

With the publicly available information that we could find, the prevalence rate of placenta previa in foreign countries is about 0.3%–0.9%, and 0.2%–1.6% in China [1, 2]. As the number of maternal abortions has experienced a trend with gradual increase in recent years, the endometrial injury has increased the prevalence of placenta previa. Placenta previa is acknowledged as a complication of late pregnancy, which consists of pernicious and non-placenta accrete previa according to the degree of the disease. It can be divided into marginal, partial and central placenta previa based on the location of the lower edge of placenta and the internal orifice of the uterus. High-risk placenta previa includes placenta accrete previa and central placenta previa, which may in- crease the risk of aggravating the condition. Not only can it lead to intractable massive hemorrhage, but it can also damage surrounding organs, and even endanger the life of maternal and fetal [3, 4]. Therefore, additional focus is necessary for clinical practice on how to effectively treat patients with high-risk placenta previa.

Conventional cesarean section is currently used in treating patients harboring high-risk placenta previa. Methods for hemostasis include uterine tamponade, suture

and oxytocin drugs, however, they fail to achieve ideal effects among some patients. Despite that several studies have showed the increasing use of balloon occlusion in the treatment of placenta previa in recent years, the method still can not completely stop the bleeding, and there were patients who suffered from active bleeding [5]. According to several studies, the combined application of balloon occlusion and uterine artery embolization can reduce the intraoperative and postoperative blood loss of patients with high-risk placenta previa undergoing cesarean section, as well as the risk of complications [6, 7]. However, limited researches are available in China. Herein, our study exerted efforts to investigate the overall effect of balloon occlusion combined with uterine artery embolization on coagulation function of patients with high-risk placenta previa during cesarean section, in order to provide insight for clinical practice in the management of the condition.

2. Materials and Methods

2.1. Clinical Background. In total, there included 38 patients with high-risk placenta previa undergoing cesarean section in our hospital from August 2019 to January 2021. The participants were randomly allocated into study group and control group, with 19 cases in each group. On one hand, in study group, the age ranged from 23 to 36 years old, with an average age of (28.83 ± 4.21) years old. The body mass index (BMI) was 23–28 kg/m^2, and the average BMI was (25.23 ± 1.03) kg/m^2. There were 2 to 5 times of pregnancy, with an average of (3.23 ± 0.76) times. There were 1 to 3 times of delivery, with average of (1.32 ± 0.19) times. The gestational age was 34 to 37 weeks, and the average of (36.87 ± 1.72) weeks. Classification: 11 cases of central placenta previa, 8 cases of placenta accrete previa. On the other hand, in the control group, the age ranged from 23 to 34 years old, with an average of (28.79 ± 4.19) years old. The body mass index was 23–27 kg/m^2, and the average body mass index was (25.17 ± 1.01) kg/m^2. There were 2 to 5 pregnancies with an average of (3.26 ± 0.74) times. There were 1 to 4 times of delivery, with an average of (1.31 ± 0.21) times. The gestational weeks ranged from 33 to 37 weeks, and an average of (36.79 ± 1.69) weeks. Classification: 10 cases of central placenta previa, 9 cases of placenta accrete previa. The general data of the two groups were comparable ($P > 0.05$). The formulation of this research protocol is in line with the relevant requirements of the Helsinki Declaration of the World Medical Association.

2.2. Selection Criteria

2.2.1. Inclusion Criteria. (1) The patients were diagnosed with high-risk placenta previa for cesarean section based on the Obstetrics and Gynecology (9th Edition) [8]; patients in late pregnancy experienced painless vaginal bleeding with unknown causes, who were diagnosed with central placenta previa or placenta accrete previa using MRI [9] or B-ultrasound [10]. (2) Single live fetus. (3) There was no history of cesarean section in central placenta previa. (4) The coagulation function was normal. (5) The function of endocrine system was normal. (6) Complete clinical information. (7) All patients and their

families had informed consent. (8) No allergy to contrast medium.

2.2.2. Exclusion Criteria. (1) Patients with abnormal mental state and poor compliance. (2) Patients with severe malig- nant tumor. (3) Patients with abnormal circulatory system or liver and kidney function. (4) Patients with tuberculosis, syphilis, AIDS and other infectious diseases. (5) Previous thrombosis. (6) Patients with chronic pain or peripheral neuropathy. (7) The skin of abdominal wall was damaged and infected (8) Previous history of smoking, drinking, psychosis, motion sickness or postoperative nausea and vomiting. (9) Patients with other pregnancy complications.

3. Methods

The diagnosis and treatment mode of high-risk placenta previa were operated. Doctors from relevant departments, including neonatology department, imaging department, obstetrics department, vascular surgery department, urology department, interventional department, operating room, laboratory department, etc., should consult. Pain MRI and color Doppler ultrasound would be used to understand the placental location, implantation, scope and relationship with surrounding tissues, determine the location of uterine in- cision, and the appropriate operation time and operation plan. Enough blood was prepared. All parturients underwent elective surgery in operating room.

The control group was given conventional cesarean section. In operating room, patients were given general anesthesia. The placental attachment site was avoided as the uterine body incision to deliver the fetus. Routine disin- fection was performed for cesarean section. After entering the abdomen, the uterine wall was cut, and the fetus was delivered and handed over to the neonatal physician for treatment. 10 U oxytocin was injected into the uterine body and maintained by intravenous injection of 10 U oxytocin. The placenta was stripped by hand. The placenta tissue on the placenta accreta surface was cleaned, the bladder peri- toneum was separated, the bladder was pushed down, the lower uterine segment was exposed, the wound was sutured, and the myometrium was repaired. If uncontrollable bleeding occurs, the uterus will be removed. If there is no bleeding, conventional suture should be performed. In case of uterine atony, hemabate should be injected into uterine body in time. If excessive bleeding (more than 1000 ml) occurs continuesly, the anesthesiologists and ICU doctors should be responsible to maintain the vital signs of patients, giving anti fibrinolysis treatment, and giving warm liquid injection and keeping warm. The arterial blood gas (in- cluding K^+, Ga^+, hemoglobin, etc.) and central venous pressure should be monitored and recorded to maintain the blood pressure at 80/50 mmhg. The condition of patients was closely monitored to determine if they should transfer to the ICU or if blood transfusion was needed. After operation, the patients were given 2 U hemagglutinase.

The study group was given balloon occlusion combined with uterine artery embolization. The right femoral artery

was punctured by the modified Seldinger method. The 16 mm balloon catheter and the 8 F artery sheath were inserted. 1–2 ml contrast medium was injected. The balloon was placed about 1 cm below the opening of bilateral renal artery. After the fetus was delivered and the umbilical cord was cut off, the balloon was filled. After the placenta was stripped and the placenta tissue was cleaned, the bleeding area of the uterine wall was sutured, and the contrast medium in the balloon was extracted. The balloon was filled every 5 minutes. After hemostasis, bilateral internal iliac arteriography was performed to determine the route of uterine artery. Selective catheterization of bilateral uterine artery was performed, and gelfoam particles were used for emboli- zation. The bandage was removed after 24 hours in bed.

3.1. Observation Indexes. The operation time, intraoperative blood loss, plasma injection volume, and hospital stay were measured and recorded. The postoperative coagulation function indexes, including thrombin time (TT), fibrinogen (FBI), activated partial thromboplastin time (APTT) and prothrombin time (PT), were recorded. Neonatal Apgar score and postoperative complications were compared between the two groups.

Laboratory indicators: 3–5 ml elbow venous blood was collected from patients after operation, and stored in 30°C refrigerator after centrifugation. The levels of TT, FBI, APTT and PT were analyzed by automatic biochemical analyzer. The kits were purchased from Shanghai Hanfei Medical Instrument Co., Ltd. and strictly operated according to the reagent instructions.

Postoperative complications, including puerperal in- fection, poor wound healing, ICU transfer, lower limb thrombosis, disseminated intravascular coagulation and hysterectomy rate, were compared.

3.2. Statistical Methods. SPSS 21.0 software was utilized to analyze the data. The operation time, intraoperative blood loss, plasma injection volume, hospital stay, postoperative coagulation function and other measurement data were analyzed, expressed as $\bar{x} \pm s$ using t test. The counting data were expressed as percentage (%) and chi square χ^2 was used. A $P < 0.05$ represents significant difference.

4. Results

Comparison of operation time, intraoperative blood loss, plasma injection volume and hospital stay between the two groups.

The intraoperative blood loss, plasma injection volume and hospital stay of the study group were significantly lower compared with the control group ($P < 0.05$). However, the operation times were comparable between the two groups ($P > 0.05$), as laid out Table 1.

4.1. Comparison of Coagulation Function between the Two Groups. The study group showed remarkably lower levels of TT, APTT and PT, and higher level of FBI than the control group ($P < 0.05$), as shown in Table 2.

4.2. Comparison of Apgar Score between the Two Groups. Apgar 1-min and 5-min scores of newborns were comparable between the two groups ($P > 0.05$), as shown in Table 3.

4.3. Comparison of Postoperative Complications between the Two Groups. Compared with the control group, the incidence of postoperative complications in the study group wassignificantly lower ($P < 0.05$), as laid out in Table 4.

5. Discussion

Placenta previa is an obstetric complication in which the placenta is inserted in the lower uterine segment, generally 28 weeks after pregnancy [11]. Recent studies have shown that, the incidence of high-risk placenta previa has experi- enced a climbing trend as the increase of cesarean section rate [12]. In addition, it was reported that the application of In Vitro Fertilization (IVF) also increased the risk of placental anomalies [13]. Severe postpartum hemorrhage is prone to occur in the process of cesarean section. Its main characteristics are intractable hemorrhage and placenta accreta. Improper treatment can pose a serious threat to the safety of mother and baby. A study [14] explicated that the median bleeding volume of patients with high-risk placenta previa ranged from 2000 ml to 7800 ml. In the past, hysterectomy was often used to treat intractable postpartum hemorrhage, but it failed to reduce the amount of bleeding, and even led to infertility. The operation of preserving uterusmay result in massive hemorrhage and various complica- tions. Hence appropriate management is of great signifi- cance to treat high-risk placenta previa, to reduce the amount of bleeding and the incidence of complications.

Based on a recent study [15], the application of inter-
ventional therapy in postpartum hemorrhage showed a good hemostatic effect. In 2009, the society of Obstetrics and Gynecology in abroad has encouraged obstetricians and interventional physicians to give interventional treatment to patients with high suspected or clear risk of massive hem- orrhage of placenta accreta before surgery. Vascular inter- ventional therapy is able to effectively stop bleeding by embolizing bleeding vessels directly. In recent years, as the advances of interventional therapy in placenta previa, bal- loon occlusion has been gradually acknowleged and applied in the treatment of placenta previa [16]. It was reported that preventive placement of balloon catheter was an effective method to manage severe hemorrhage of placenta previa, which could reduce intraoperative blood loss, perioperative hemostasis and reduce hysterectomy [17]. Due to the pla- cental attachment site of patients with high-risk placenta previa, the physiological contraction function is reduced, and a large area of blood sinus is open, a large amount of bleeding may occur in a short time. Another study revealed that placenta previa was an independent risk factor for maternal bleeding [18]. Moreover, the blood can affect the operation due to unclear surgical field of vision. In addition, the placenta accreta muscle layer is difficult to peel off, which can lead to the aggravation of the disease. When the balloon is filled, it can block most of the pelvic blood supply below

Table 1: Comparison of operation time, intraoperative blood loss, plasma injection volume and hospital stay between the two groups ($\bar{x} \pm s$).

Group	n	Operation time (min)	Intraoperative blood loss (ml)	Plasma injection volume (ml)	Hospital stay (d)
Control group	19	118.73 ± 18.73	803.28 ± 123.29	348.91 ± 37.98	7.03 ± 0.23
Study group	19	109.83 ± 17.27	1391.91 ± 132.87	763.29 ± 45.29	12.03 ± 0.34
t		1.523	−14.155	−30.559	−53.094
P		0.136	<0.001	<0.001	<0.001

Table 2: Comparison of coagulation function indexes between the two groups ($\bar{x} \pm s$).

Group	n	PT (s)	FBI (g/L)	APTT (s)	TT (s)
Control group	19	12.49 ± 1.08	3.12 ± 0.29	45.39 ± 2.76	19.02 ± 1.13
Study group	19	10.56 ± 1.02	3.99 ± 0.32	35.01 ± 2.33	15.13 ± 1.09
t		5.663	−8.781	12.526	10.799
P		<0.001	<0.001	<0.001	<0.001

Table 3: Comparison of Apgar score between the two groups ($\bar{x} \pm s$, points).

Group	n	1-min score	5-min score
Control group	19	8.87 ± 0.27	9.65 ± 0.23
Study group	19	8.91 ± 0.24	9.72 ± 0.15
t		−0.483	−1.111
P		0.632	0.274

Table 4: Comparison of postoperative complications between the two groups.

Group	n	Puerperal infection	Poor wound healing	ICU transfer	Lower limb thrombosis	DIC	Hysterectomy rate	Total incidence
Control group	19	0	1	3	0	0	3	7 (36.84)
Study group	19	0	0	0	1	0	0	1 (5.26)
t								5.699
P								0.017

the abdominal aorta. Furthermore, it is conducive to the operation and reduce the operation time, in terms of slowing down the blood flow and reducing the intraoperative blood loss with clear surgical vision.

According to Qian et al. [19], the treatment of placenta accrete previa with abdominal aortic balloon occlusion combined with uterine artery embolization can effectively reduce the amount of blood transfusion and bleeding, shorten the operation time, the hysterectomy rate and the hospital stay. Wu et al. [20] pointed out, that the treatment of patients with placenta accrete previa by abdominal aorta balloon occlusion combined with uterine artery emboliza- tion can effectively reduce the amount of bleeding during operation, reduce the rate of hysterectomy and the incidence of postoperative complications. Based on our results, the amount of blood loss, plasma injection and hospital stay of the study group were markedly lower compared with the control group ($P < 0.05$), and the operation times of the two groups were comparable ($P > 0.05$). This suggested that balloon occlusion combined with uterine artery emboliza- tion is able to reduce the amount of blood loss and the amount of plasma injection, without increasing the opera- tion time, which is also able to shorten the length of hospital stay. The results may be due to the rich blood supply of the uterus during pregnancy, mainly including uterine artery and other internal iliac artery branches, ovarian artery and

other collateral circulation. Patients with high-risk placenta previa have abundant collateral circulation, abnormal pro- liferative blood vessels and dense venous plexus, hence uterine artery embolization alone can not achieve satisfac- tory hemostatic effect. It is necessary to block the blood flow of abdominal aorta embolization and its downstream branches with balloon occlusion before operation, so as to achieve satisfactory hemostatic effect and support the re- covery of patients.

During pregnancy and delivery, the functions of coag- ulation, anticoagulation and fibrinolysis are changed amongnormal pregnant women. The levels of thrombin and co- agulation factors in blood are increased, while the functions of anticoagulation and fibrinolysis are decreased, and the blood is in hypercoagulable state. The above functions are widely known as the natural protection function of pregnant women, which can effectively prevent postpartum hemor- rhage and provide material basis for rapid hemostasis. Postpartum hemorrhage is a serious obstetric complication, especially in patients with high-risk placenta previa. The abnormal coagulation function of patients is an important factor leading to postpartum hemorrhage and disseminated intravascular coagulation [21]. Therefore, monitoring the coagulation function of patients with high-risk placenta previa can help effectively evaluate the risk of bleeding and hemostatic effect, which is pivotal for clinical practice. Our

results demonstrated that the levels of TT, APTT and PT in the study group were lower, and the level of FBI was higher compared with the control group ($P < 0.05$), suggesting that balloon occlusion combined with uterine artery emboliza- tion can improve the coagulation function of patients with high-risk placenta previa during cesarean section, and prevent postpartum hemorrhage.

According to the results of our study, the Apgar 1-min and 5-min scores of newborns were comparable between the two groups ($P > 0.05$), suggesting that balloon occlusion combined with uterine artery embolization failed to affect the Apgar scores of newborns with high-risk placenta previa undergoing cesarean section. The reasons behind can be concluded as follows: (1) according to the International Commission on Radiation Protection (ICRP), the X-ray exposure dose of the fetus less than 100 mGy can not affect the tissue development function of the fetus, and the ra- diation dose in this study was less than the dose standard. (2) In addition, for patients with high-risk placenta previa during cesarean section, the balloon was not filled before the delivery of the fetus, hence the blood supply of the uterus was not blocked to affect the blood oxygen exchange be- tween the uterus and placenta. Therefore, fetal intrauterine hypoxia can not occur, which may be an important reason for not affecting neonatal Apgar score.

Balloon occlusion is able to control the filling volume of balloon, and the operation is simple. It can effectively avoid the injury of vascular wall, prevent the formation of thrombosis and injury of arterial wall. After delivery of the fetus, the balloon is filled and the blood vessels below the abdominal aorta plane are blocked, which can effectively stop bleeding. After the hemostatic effect is achieved, the balloon is relaxed and the blood flow is restored, which can prevent the occurrence of complications such as lower limb ischemic necrosis caused by long-term compression [22]. Our results depicted that the incidence of postop- erative complications in the study group was remarkably lower compared with the control group ($P < 0.05$), indi- cating that balloon occlusion combined with uterine ar- tery embolization in the treatment of high-risk placenta previa patients with cesarean section had less postoper- ative complications and with safety profile. However, one patients suffered from lower limb thrombosis in the study group. Given that the patient was elderly maternal (36 years old), and discharged after thrombolytic therapy with longer postoperative bedridden time, it is worth noting that the blood was in a hypercoagulable state, and balloon occlusion may damage vascular intima. The condition and risk should be conprehensively evaluated before opera- tion, including the skin color and dorsalis pedis artery pulse of patients after operation. And doctors should encourage patients to turn over early after operation, and carry out massage on lower limbs, to avoid the occurrence of related complications.

Taken together, the combined approach of balloon oc- clusion and uterine artery embolization elicited superior outcomes in the management of patients with high-risk placenta previa during cesarean section. Not only can it reduce the amount of blood loss and plasma injection, but it

can also shorten the length of hospital stay, and improve coagulation function, without affecting neonatal Apgar score. In addition, the approach brought no risk for in- creasing the incidence of postoperative complications, which was believed available for clinical practice. However, considering the small sample size of this study, more studies are needed to further explore the effect of the balloon occlusion combined with uterine artery embolization on the fertility of patients.

Data Availability

The datasets generated and analyzed during the current study are available from the corresponding author on rea- sonable request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Authors' Contributions

Xiaoli Xu Xiayun Zhu contributed equally to this paper.

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International Journal of Clinical

Malakian *et al. BMC Pediatrics* (2021) 21:301
https://doi.org/10.1186/s12887-021-02741-w

BMC Pediatrics

RESEARCH ARTICLE Open Access

Non-invasive duo positive airway pressure ventilation versus na continuous positiveairway pressure in preterm infants with respiratory distress syndrome: a randomized controlled trial

Arash Malakian[1], Mohammad Reza Aramesh[1], Mina Agahin[1] and Masoud Dehdashtian[1,2*]

Abstract

Background: The most common cause of respiratory failure in premature infants is respiratory distress syndrome. Historically, respiratory distress syndrome has been treated by intratracheal surfactant injection followed by mechanical ventilation. In view of the risk of pulmonary injury associated with mechanical ventilation and subsequent chronic pulmonary lung disease, less invasive treatment modalities have been suggested to reduce pulmonary complications.

Methods: 148 neonates (with gestational age of 28 to 34 weeks) with respiratory distress syndrome admitted to Imam Khomeini Hospital in Ahwaz in 2018 were enrolled in this clinical trial study. 74 neonates were assigned to duo positive airway pressure (NDUOPAP) group and 74 neonates to nasal continuous positive airway pressure (NCPAP) group. The primary outcome in this study was failure of N-DUOPAP and NCPAP treatments within the first 72 h after birth and secondary outcomes included treatment complications.

Results: there was not significant difference between DUOPAP (4.1 %) and NCPAP (8.1 %) in treatment failure at the first 72 h of birth ($p = 0.494$), but non-invasive ventilation time was less in the DUOPAP group ($p = 0.004$). There were not significant differences in the frequency of patent ductus arteriosus (PDA), pneumothorax, intraventricular hemorrhage (IVH) and bronchopulmonary dysplasia (BPD), apnea and mortality between the two groups. Need for repeated doses of surfactant ($p = 0.042$) in the NDUOPAP group was significantly lower than that of the NCPAP group. The duration of oxygen therapy in the NDUOPAP group was significantly lower than that of the NCPAP group ($p = 0.034$). Also, the duration of hospitalization in the NDUOPAP group was shorter than that of the NCPAP group ($p = 0.002$).

Conclusions: In the present study, DUOPAP compared to NCPAP did not reduce the need for mechanical ventilation during the first 72 h of birth, but the duration of non-invasive ventilation and oxygen demand, the need for multiple doses of surfactant and length of stay in the DUOPAP group were less than those in the CPAP group.

* Correspondence: dehdashtian@ajums.ac.ir; m.dehdashtian@gmail.com
[1]Department of Pediatrics, Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical sciences, Ahvaz, Iran
[2]Department of Paediatrics, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

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Trial registration: IRCT20180821040847N1, Approved on 2018-09-10.

Keywords: Duo positive airway pressure, Nasal continuous positive airway pressure, Preterm infants, Respiratory distress syndrome

Background

Respiratory insufficiency is a common problem in term infants and preterm neonates in neonatal intensive care units. In premature infants, the most common cause of respiratory failure is respiratory distress syndrome (RDS) [1]. RDS remains the leading cause of adverse events and mortality in premature infants, affecting approxi- mately 26% of infants born between 32 and 34 weeks of gestation [2].

Historically RDS has been treated by injection of sur- factant into the trachea followed by mechanical ventila- tion. Because of the risk of pulmonary injury associated with mechanical ventilation, followed by the develop- ment of chronic lung disease and other complications including subglottic stenosis and pneumonia, less inva- sive therapies have been proposed to reduce pulmonary complications [3].

In recent years, studies have focused on non-invasive ventilation techniques to reduce the need for mechanical ventilation and its associated pulmonary complications [4]. There are currently a number of non-invasive re- spiratory care options for preterm infants, including nasal continuous positive airway pressure (NCPAP), nasal intermittent positive ventilation (NIPPV), nasal high frequency oscillation (NHFO) and high flow nasal cannula (HFNC) [5].

One of the common clinical strategies is the use of NCPAP, which has been shown to be effective in reducing ventilation through endotracheal tube and chronic pulmonary disease in very preterm infants [6, 7]. However, in randomized clinical trials, some patients undergoing NCPAP still required intubation due to worsening of patients' clinical status [8, 9], because NCPAP does not necessarily improve alveolar ventilation or CO_2 elimination [10].

Currently, NCPAP is the standard treatment for respiratory distress syndrome (RDS) [11]. Duo positive airway pressure (DUOPAP) is a new respiratory support mode consisting of a combination of two CPAP levels. In fact, DUOPAP mode is same as bilevel positive airway pressure (BIPAP). In the DUOPAP mode, PDuo is the maximum pressure that is alternately applied to the previous baseline CPAP. Breathing rate is the number of PDuo applied per minute [12]. DUOPAP respiratory support increases mean airway pressure, tidal volume and minute ventilation and subsequently improves hypoxia and CO_2 retention [12].

In this study, it is hypothesized that early use of NDUOPAP reduces the need for invasive respiratory support compared to NCPAP in preterm infants with respiratory distress syndrome.

Methods

This study was performed in a Neonatal Intensive Care Unit at Imam Khomeini Hospital of Ahvaz Jundishapur University of Medical Sciences in Ahvaz, Iran, during 2018–2019. Premature infants with gestational age of 28 to 34 weeks who had respiratory distress syndrome and their respiratory distress score based on the Silverman- Anderson table was 6 and 7 during the first 6 h of birth were enrolled [13–16].

Exclusion criteria included presence of major anomal- ies, airway anomaly, severe cardiovascular instability, re- spiratory distress secondary to severe asphyxia (Apgar score ≤ 3 at 1 and 5 min and umbilical cord blood pH < 7.1), parental discontent, gestational age less than 28 weeks, cyanotic heart disease, meconium aspiration syn- drome, diaphragmatic hernia, invasive mechanical venti- lation started from the beginning of hospitalization, pulmonary hemorrhage, lack of effective spontaneous breathing, metabolic disease during hospitalization and respiratory problems due to neuromuscular diseases and sepsis [12–16].

All parents were required to complete and write an informed consent form before the neonates were en- rolled in the study, according to the Ethics Committee of Jundishapur University of Medical Sciences (IR.A- JUMS.REC.1397.365). Also, the present study was regis- tered in the Iranian Clinical Trial Documentation Office on 10.9.2018 (IRCT: 2,018,082 1040847NI).

In this unmasked randomized trial, neonates were ran- domly divided into two groups of NDUOPAP and NCPAP.NDUOPAP group was considered group A and NCPAP group as group B. Based on the https://www.Sealedenvelope.com/simple–randomizer/V1/lists, the list was prepared. Six blocks were initially considered, in- cluding AABB, ABAB, ABBA, BABA, BAAB, BBAA and

each block was assigned a code between 1 and 6. The statistical consultant randomly selected a number from 1 to 6 to create a random sequence and as a result, the in- fants were randomized into the two groups of A and B. Sample size was calculated by formula and according to the sample size of Zhou et al. [12] article, where the failure rates of non-invasive NDUOPAP and NCPAP

treatment were 4.44 and 22.5 %, respectively, 67 patients were studied in each group. Due to the probability of at least 10 % sample attrition, 7 individuals were added to each group, resulting in a sample size of 148 (74 subjects per group). After birth, the necessary resuscitation pro- cedures were performed by a trained resuscitation team and a senior physician assistant for all infants who weighed below 1500 g according to the NICU protocol and infants were transited to NICU in presence of a spe- cialized NICU nurse under T-piece respiratory support (Fisher & paykel Healthcare, New Zealand) [16].

In the NICU, infants who were eligible for inclusion were randomly assigned to one of NDUOPAP or NCPAP groups. In infants of the DUOPAP group Fabian device (Acutronic, Switzerland, Infant flow driver) was used, which was connected to the infant via standard nasal tubes and injectors through a nasal prong. For ne- onates in this group, baseline parameters including PDuo (8 cm H_2O) and CPAP (5 cm H_2O), FIO_2 40 %, in- halation time of 0.5 s, and respiratory rate between 30 and 40 breaths per minute were adjusted. Based on clinical examination, arterial blood gas (ABG) and SPO_2, device parameters were changed. The highest acceptable CPAP and PDuo levels were less than 8 cm H_2O and
15 cm H_2O, respectively, and the maximum FIO_2 acceptable to continue treatment was 60 %. The goal of altering device setting was reaching SPO_2 above 90 % in the right hand, PaO_2 above 50 mmHg, $PaCO_2$ less than 50 mmHg, pH above 7.25 and lack of respiratory distress on physical examination [12, 13].

In the NCPAP group, infants were subjected to Fabian device (Acutronic, Switzerland, Infant flow driver). The device was connected to the infant by standard injectors and tubes through the nasal prong. In the NCPAP group the initial parameters of the device were CPAP (5 cm H_2O) and FIO_2 40 % and based on clinical examination, ABG and SPO_2 changes of device parameters were per- formed. The highest acceptable CPAP level was less than or equal to 8 cm H_2O and the maximum FIO_2 ac- ceptable to continue treatment was 60 %. The target was O_2 saturation above 90 % in the right hand ($PaO_2 \geq 50$ cm H_2O, $PaCO_2 < 50$ cm H_2O, and pH ≥ 7.25) and the absence of respiratory distress on phys-ical examination [12, 13].

In both groups, based on existing therapeutic guides and under the direct supervision of the researcher, infants requiring FIO_2 over 40 % with CPAP > 5 cm H_2O to maintain O_2saturation in the right hand be- tween 90 and 95 %, 100 mg /kg surfactant (Survanta) were administered using the INSURE (Intubation, Surfactant and Extubation) method by a skilled prac- titioner who had been predetermined [17]. After INSURE, the infant received the same non-invasive ventilation used before INSURE.

A feeding tube was inserted to remove air from the baby's stomach. O_2 saturation was monitored and re- corded by pulse oximeter and respiratory rate, heart rate was monitored continuously, and blood pressure every
2 h. In infants requiring a FIO_2 greater than 40 % to maintain SPO_2 within the acceptable range (90–95 %), surfactant was re-administered after 6 h after the last surfactant administration and as needed for a full course of treatment (maximum of 4 doses).

ABG was measured on admission (all subjects), in cases in need of intervention, one hour after the inter- vention as well as every 12 h thereafter, and before and after surfactant administration and the results were recorded in a special form. Based on the results an ap- propriate intervention was carried out when necessary [12, 16, 18, 19]. Occurrence of treatment failure as well as duration of intervention, pneumothorax, BPD, PDA, apnea, occurrence of death, IVH, duration of oxygen therapy, length of hospital stays and mean airway pres- sure were recorded every 6 h in each group. As decided, after improvement in patient's condition and O_2 satur- ation maintenance for 6 h, we went on to reduce the de- vice settings, such that if in DUOPAP FIO_2 was less than 30 % and CPAP and PDuo were less than or equal to 3 cm of water and 5 cm of water, respectively, and the infant was breathing continuously and ABG was normal for 24 h, the infant was disconnected from the apparatus and placed under oxyhood inhaling a mixture of air and oxygen with FIO_2 30–40 % and a flow of 5 to 10 L per minute depending on the size of the hood and patient's O_2 saturation [12].

In the CPAP group if the neonate was clinically stable (defined as respiratory rate lower than 60 per minute, no apnea and O_2saturation > 90 % 0n right hand) parame- ters were reduced to: CPAP ≤ 3 cm H_2O and FIO_2 < 30 %. If neonate condition was stable for the preceding 24 h, the neonate was separated from CPAP [12].

All of the participants received antibiotics, caffeine as prophylaxis for apnea of prematurity and appropriate fluid and electrolyte solutions.

The primary outcome was the need for endotracheal intubation within the first 72 h of treatment. Treatment failure criteria included at least one of the following: pH < 7.2, $PaCO_2$ > 60 mmHg, PaO2 < 50 mmHg with FIO_2 > 60 %, CPAP > 8 cm H_2O in NCPAP group and PDuo > 15 cm H_2O, CPAP > 8 cm H_2O, and FIO2 > 60 %
in NDUOPAP group or worsening of the clinical condi- tion (increased respiratory distress due to severe retrac- tion) or prolonged apnea (stopping breathing for more than 20 s) or recurring apnea more than 2 times in 24 h with cyanosis and bradycardia (PR ≤ 100 / min) requiring ventilation with a bag and mask [12, 13, 20].

Secondary outcomes included duration of non-invasive ventilation, duration of oxygen therapy, duration of

hospitalization, occurrence of IVH, pneumothorax, BPD, PDA, apnea, and death. All patients underwent echocar- diogram within 48 h of birth and afterward if needed. Brain ultrasonography for diagnosing IVH was per- formed on the third and seventh days. Pneumothorax was diagnosed on the basis of chest x-ray and transillu- mination [11].

Statistical analysis

In quantitative variables mean and standard deviation were used to describe the data in addition to median and interquartile range. Frequency and percentage were used to describe the data. Normality of the data was ana- lyzed using Kolmogorov-Smirnov test and Q-Q chart. Data were analyzed using chi-square, Fisher's exact test, t-test and Mann-Whitney test. Significance level was set at *P*-value less than 0.05. All analyses were performed using SPSS version 22.

Results

According to Fig. 1, the study population consisted of 160 neonates born between 28 and 34 weeks of gestation with a diagnosis of RDS. A total of 12 neonates were ex- cluded: 10 due to not meeting the inclusion criteria and 2 due to non-cooperation. Therefore, this study was per- formed on 148 infants, 74 treated with NCPAP and 74 treated with NDOUPAP.

The social and demographic characteristics of the in- fants are presented in Table 1. There were no significant differences in baseline characteristic. The level of arterial PCO_2 one hour after inclusion in the NDUOPAP group ($PaCO_2$:44.06 mmHg) was significantly lower than that of NCPAP ($PaCO_2$:46.51 mmHg) and this difference was significant ($p = 0.029$). Arterial PO_2 level was higher one hour after start of treatment in the NDUOPAP group (72.21 mmHg) than NCPAP (67.01 mmHg) ($p < 0.001$).

There was no significant difference in the primary outcome of treatment failure during the first 72 h of birth between the NDUOPAP (3[4.1 %]) and NCPAP (6[8.1 %]) groups ($p = 0.494$); Table 2.

The duration of non-invasive ventilation was shorter in the NDUOPAP group and this difference was signifi- cant (CPAP = 50.12 ± 23.83 h vs. DUOPAP = 39.18 ± 18.14 h; $p = 0.004$); Table 2.

The duration of oxygen therapy in the NDUOPAP group was shorter than that of NCPAP group (CPAP = 107.45 vs. DUOPAP = 75.48; $p = 0.034$;) Table 2.

Duration of hospitalization in the NDUOPAP group was shorter than that of NCPAP (CPAP = 668.08 h vs. DUOPAP = 495.88 h ; $p = 0.02$) Table 2.

Other outcomes including IVH, pneumothorax, BPD, PDA, apnea and death were not significantly different ($p > 0.05$); Table 2.

The mean airway pressure level in the NDUOPAP group was higher than that of the NCPAP group, but

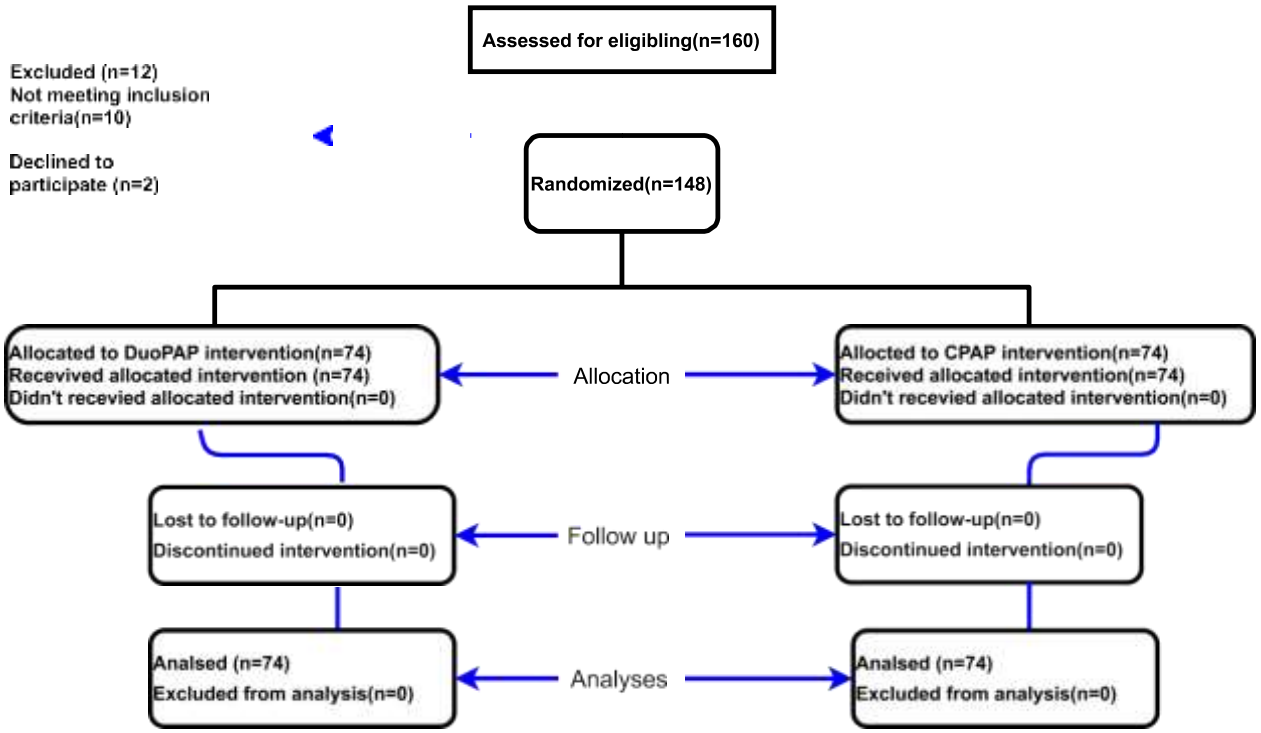

Fig. 1 Consort. Transparent reporting of trials

Table 1 Demographic and clinical Data in the study Groups

Characteristic	DUOPAP	CPAP	*P* value
Male, n (%)	40(54.1%)	32(43.2)	0.188
Female, n (%)	34(45.9%)	42(56.8)	
Cesarean delivery, n (%)	52(70.3%)	57(77%)	0.351
Vaginal delivery, n (%)	22(29.7%)	17(23%)	
Gestational age, weeks (mean ± SD)	31.32±1.53	31.13±1.77	0.618
Median (IQR)	31.55(2.1)	31.35(2.8)	
Body weight, gr (mean ±SD)	1415±233.15	1377.91±260.24	0.357
Antenatal steroids, n (%) First does	70(94.6%)	68(91.9%)	0.798
Antenatal steroids, n (%) second dose	2(2.7%)	3(4.1%)	
Without Antenatal steroids, n (%)	2(2.7%)	3(4.1%)	
APGAR 1 min (mean+ SD)	6.15±1.08	6.08±0.89	0.819
Median (IQR)	6(2)	6(2)	
APGAR 5 min (mean± SD)	7.69 ±0.79	7.70±0/81	0.928
Median (IQR)	8(1)	8(1)	
PPROM, n (%)	12(17.6%)	7(9.6%)	0.161
Age Mother, yrs. (mean ± SD) Mean IQR	30.08±7.44	29.24±6.59	0.470
Gestational age group, n (%)			
28-30 weeks	12 (16%)	19 (26%)	0.879
30-32 weeks	34 (46%)	23 (31%)	
32-34 weeks	28 (38%)	32 (43%)	

n number, *SD* Standard Deviation, *IQR* Inter Quartile Range

Table 2 Treatment effect and complication in study groups

Characteristic	NDUOPAP	NCPAP	*P* value
Failure in first 72 h, n (%)	3(4.1%)	6(8.1%)	0.494
Duration of Noninvasive Respiratory support (hr) (mean± SD)	39.18±18.14	50.12±23.83	0.004
Duration of oxygen therapy (hr) (mean± SD)	75.48±26.06	107.45±156.06	0.034
Duration of hospitalization (hr) Mean ± SD)	495.88±310.11	668.08±360.46	0.002
Pneumothorax, n median (IQR)	0(0)	2(2.7)	0.497
IVH, n (%) Grade I & II	3(4.1)	5(6.8)	0.719
PDA mild, n (%)	4(5.4%)	5(6.8%)	1
PDA moderate, n (%)	4(5.4)	3(4.1)	1
BPD, n (%)	0(0)	1(1.4)	0.319
Apnea, n (%)	1(1.4%)	4(5.4%)	0.366
Deaths, n (%)	2(2.7%)	5(6.8%)	0.442
Surfactant First dose, n (%)	31(41.9%)	39(52.7%)	0.042
Surfactant Secondary dose, n (%)	13(17.6%)	20(27%)	0.042
Surfactant 3 dose, n (%)	2(2.7%)	1(1.4%)	0.042

h hour, *PDA* Patent Ductus Arteriosus, *n* number, *BPD* Bronchopulmonary dysplasia, *IQR* Inter Quartile Range, *IVH* Intra Ventricular hemorrhage

there was no significant difference between the two groups in terms of mean airway pressure at 72 h after birth.

Discussion

In recent years, studies have focused on non-invasive ventilation techniques to reduce the need for mechanical ventilation and its associated pulmonary complications [4]. Since 1970, noninvasive ventilation has been widely used in infants with CPAP. Studies have shown that CPAP reduces the need for oxygen dependence, respira- tory rate and the need for mechanical ventilation [21, 22].

However, non-invasive BIPAP ventilation during the respiratory cycle produces two levels of CPAP with fre- quency and duration as determined by the physician. Therefore, in theory BIPAP should perform better in al- veolar deployment, functional residual capacity (FRC) and improvement respiratory function than CPAP. How- ever, this has not yet been validated in clinical studies, and some studies have not yet demonstrated a clear link between BPD and non-invasive ventilation [23–26]. In this context, the present study aimed to compare the two non-invasive ventilation methods of NDUOPAP and NCPAP among 148 preterm infants with respiratory dis- tress syndrome aged 28 to 34 weeks. Because infants weighing less than 1000 g and under 28 weeks of gesta- tion are usually intubated and undergo mechanical ven- tilation, they were not included in this study [27, 28].

In the present study, the need for endotracheal intub- ation in the first 72 h of birth was not significantly different between the two groups ($p = 0.494$), which is similar to the results of Gao et al. [29], Aguiar et al. [30] and Victor S et al. [31] However, in the study of Zhou et al. [12] and Kong et al. [18], the need for endotracheal intubation was significantly lower in the NDUOPAP group than in the NCPAP group.

There was no statistically significant difference be- tween the NDUOPAP and NCPAP groups in the present study. However, since the number of treatment failures in this study was three in the NDUOPAP group and six in the NCPAP group, despite the nonsignificant statis- tical difference between the two groups, this difference was clinically remarkable, which requires further investi- gations with larger sample sizes.

In this study, the amounts of PCO_2 one hour after treatment in the NDUOPAP and NCPAP groups were 44.06 ± 4.11 mmHg and 46.51 ± 3.86 mmHg, respect- ively, which was statistically significant ($p = 0.029$), although this difference isn't clinically considerable. This finding is consistent with the study of Zhou et al. [12] and Kong et al. [18]. The reason for this may be the im- provement of the minute ventilation caused by the use of the NDUOPAP method [12].

In the present study, arterial blood PaO_2 levels were also compared one hour after treatment in the NDUO- PAP and NCPAP neonates, which were 72.21 ± 5.37 mmHg and 67.01 ± 6.57 mmHg, respectively, showing a significant difference between the two groups. This find- ing is also justified by the use of alveolar volume, flow and increased mean airway pressure (MAP) in patients treated with NDUOPAP [12, 32]. The findings of our study were similar to those of Zhou et al. [12] and Kong et al. [18].

In the present study, the mean duration of non- invasive ventilation between the NDUOPAP and NCPAP groups was 39.18 ± 18.14 h and 50.12 ± 23.83 h, respect- ively, which were significantly different (p = 0.004). This could be due to improved use of alveoli and accelerated production of surfactant. This significant difference may be the result of improved blood gas exchange in the neo- nate treated with NDUOPAP [11]. These findings were in agreement with the results of Lista et al. [19] and Arora et al. [32]. In the study of Zhou et al., the duration of non- invasive ventilation was similar in both NDUO- PAP and NCPAP groups [12]. Also, in the study of GAO et al., no significant difference was found in the duration of noninvasive ventilation between the three groups of NCPAP, BIPAP and SBIPAP [29].

The duration of oxygen therapy in our study in the two groups NDUOPAP and NCPAP was 75.48 and 107.45 h, respectively, indicating a significant difference between the two groups (p = 0.034). This is also justified by improved alveolar deployment, improvement respira- tory function and early respiratory system stability in patients treated under NDUOPAP treatment. These findings are consistent with those of Arora et al. [32] and Lista et al. [19].

The duration of hospitalization in the NDUOPAP and NCPAP groups was 495.88 and 668.08 h, respectively. There was a statistically significant difference between the two groups (P = 0.002). The results were consistent with those of Lista et al. [19] and Arora et al. [32]. This may be due to lower duration of non-invasive ventilation and oxygen therapy and earlier stabilization of the pa- tient's respiratory status.

The need for surfactant administration was also studied in both groups. The need for surfactant ad- ministration was significantly lower in NDUOPAP group (p = 0.042), which could be due to improved airway pressure and preventing alveolar collapse and thus reducing oxygen demand [33]. Alveolar stability during inhalation and exhalation may accelerate the production of surfactant and, on the other hand, achieve the ideal alveolar distribution of surfactant on alveolar surface. However, to prove this, separate studies are needed with larger sample sizes. In a study by Ricotta et al. in 2013, there was no

significant difference between multiple doses of sur- factant in the two groups of BiPAP and NIPPV [34].

In this study mortality was the same in both groups, probably because the number of treatment failure and prematurity complications were similar in both groups, which is similar to the studies of Arora et al. [32], Salvo et al. [35], and Gao et al. [29]. There was no significant difference between the two groups in terms of presence pneumothorax (p = 0.497), which is consistent with the results of Zhou et al. [12] and Lista et al. [19].

Bronchopulmonary dysplasia (BDP) was not signifi- cantly different between the two groups (p = 0.319). Many studies have investigated the incidence of PBD between different modes. Zhou et al. [12], Arora et al.
[32] Rong et al. [36], and Lista et al. [19] obtained similar results.

The PDA (P = 1) and IVH (P = 0.1719) in both groups were similar, which was similar to findings of Zhou et al. [12]. Salvo's results [35] showed no significant difference in IVH and PDA rates between the CPAP, BiPAP and NSIPPV groups. There was also no significant difference in IVH rate between the two groups of BiPAP and CPAP in the study of Gao et al. [29]. Similar results were found in the study of Lista et al. [19] regarding IVH.

There was no significant difference between the two groups in the rate of apnea in the present study (P = 0.366). This may be due to the low number of neonates with apnea and the lack of significance of this variable in the present study. Nursing reports on the severity of apnea are unreliable because existing devices cannot detect obstructive apnea or mixed apnea and can only record central apnea [37].

In our study, mean airway pressure was evaluated every 6 h in both modes. P-value up to 48 h was less than 0.001 and at 69 h it was $p < 0.002$. However, at 72 h, the P-value was equal to 0. 101, which may be due to separation of some patients from the device, thus de- creasing the sample size (Table 3).

Limitations

Limitations of this study include limited sample size and exclusion of infants with gestational age less than 28 weeks in this study. A multicenter study is needed to further validate these findings.

Conclusions

In this study, NDUOPAP was compared to NCPAP and did not decrease the need for mechanical ventilation in

Table 3 Mean Airway Pressure difference during treatment in study groups

	MAP(CM/H2O) & Median		*P*-VALUE	Patient Number	
	NDUOPAP	NCPAP		NDUOPAP	NCPAP
At admit time	6.89±0.76	5.29±0.47	<0.001	74	74
	6.85(1.30)	5.10(0.70)			
After 6 Hour	6.65±1.06	5.12 ±0.63	<0.001	74	73
	6.50(1.13)	5(0.4)			
After 12 Hour	6.07± 1.03	4.75± 0.49	<0.001	72	71
	6.25(1.17)	4.90(0.50)			
After 18 Hour	5.63± 1.41	4.46± 0.72	<0.001	72	71
	5.95(2.40)	4.80(1)			
After 24 Hour	5.11± 1.20	4.28±0.85	<0.001	67	71

	5.30(2.2)	4.70(1.60)			
After 30 Hour	5.17± 1.12	4.65± 3.74	<0.001	48	58
	5.30(2.22)	4.10(1)			
After 36 Hour	4.77± 1.07	3.96± 0.66	<0.001	43	52
	4.2(1.5)	4(0.9)			
After 42 Hour	4.64± 1.02	3.69± 0.71	<0.001	40	27
	4.1(1.55)	3.6(o.9)			
After 48 Hour	4.67± 1.10	3.64± 0.76	<0.001	26	42
	4.10(1.65)	3.25(1.10)			
After 60 Hour	4.43± 0.92	3.49± 0.61	0.002	10	25
	4.20(1.35)	3.20(1)			
After 72 Hour	3.88± 0.53	3.39± 0.45	0.101	5	17
	4.10(085)	3.20(0.90)			

the first 72 h of birth, but the duration of non-invasive ventilation, duration of oxygen requirement, and duration of hospitalization in the NDUOPAP group were lower. However, further studies are needed to evaluate the potential benefits of non-invasive ventila-tion, especially for vulnerable preterm infants or low Apgar infants.

Abbreviations

ABG: Arterial blood gas; BIPAP: Bilevel positive airway pressure; BPD: Bronchopulmonary dysplasia; DUOPAP: Duo positive airway pressure; HFNC: High flow nasal cannula; IVH: Intraventricular hemorrhage; MAP: Mean airway pressure; NCPAP: Nasal continuous positive airway pressure; NHFO: Nasal high frequency oscillation; NIPPV: Nasal intermittent positive ventilation; PDA: Patent ductus arteriosus; RDS: Respiratory distress syndrome

Acknowledgements

We would like to express our deepest appreciation to the participates and their parents. This paper is issued from the fellowship thesis of Neonatology. This work was financially supported by grant U-97089 from vice chancellor for Research Affairs of Ahvaz Jundishapur University of Medical Sciences.

Authors' contributions

MD: Conceptualization, Methodology, Supervision. MA: Data curation. AM: Writing- Original draft preparation: AM and MA: Visualization, Investigation. MRA: Reviewing and Editing. All authors have read and approved the manuscript.

Funding

Ahvaz Jundishapur University of Medical Sciences (U-97089).

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by Ethical committee of The Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1397.365). Written informed consent was obtained from the legal parent of the neonate.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Received: 30 September 2020 Accepted: 26 May 2021
Published online: 06 July 2021

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Original Article

Comparison of Wound Infection in Skin Staples Versus Suturesfor Skin Closure in Patients Undergoing Caesarean Section

Maria Sajid[1], Humera Noreen[2], Shagufta Saeed Sial[3], Ismat Tanveer[4], Nighat Naheed[5]

[1]Ex Post graduate Trainee, Benazir Bhutto Hospital, Rawalpindi
[2,4]Assistant Professor of Obs/Gynae, Rawalpindi Medical University, Benazir Bhutto Hospital, Rawalpindi
[3]Professor of Obs/Gynae, Rawalpindi Medical University, Benazir Bhutto Hospital, Rawalpindi
[5]Senior Registrar of Obs/Gynae, Rawalpindi Medical University, Benazir Bhutto Hospital, Rawalpindi

Correspondence: *Dr Humera Noreen*
Assistant Professor, Gynae/Obs
Benazir Bhutto Hospital, Rawalpindi
humeranoreen@ymail.com

Abstract

Objective: To compare the frequency of wound infection in skin staples versus sutures for skin closure in patients undergoing caesarean section.

Methodology: The randomized control trial study was conducted in the Department of Obstetrics & Gynaecology, Benazir Bhutto Hospital, Rawalpindi from 4th February 2015 to 3rd September 2015. A total of 654 cases were included in the study. Patients were divided into two groups. Group A was allotted for Skin Staples and Group B for sutures. Caesarean section was performed following the departmental protocols and skin closure was done according to randomization. A wound infection was recorded.

Results: In this study, the mean age of patients was the same in both groups (29.64 ± 4.17 vs. 29.58 ± 4.54 years) respectively. Mean gestational age was also the same (38.48 ± 0.65 vs 38.57 ± 0.62). In skin staples group 53(16.2%) females underwent elective c-section and 274 (83.8%) emergency c-section. In sutures group 63(19.3%) cases underwent elective and 264(80.7%) cases had emergency c-section, p-value = 0.306. In skin staples group 40(12.2%) patients developed wound infection and in sutures group 19(5.8%) females got wound infection within 7th post-operative day. Wound infection was significantly lower in suture groups as compared to staples groups, p-value = 0.04.

Conclusion: It is concluded that closure of the skin incision at caesarean delivery with the suture is associated with decrease incidence of wound infection as compared to staples.

Keywords: Caesarean section, skin closure, skin staples, sutures, complication, wound infection.

Cite this article as: Sajid M, Noreen H, Sial SS, Tanveer I, Naheed N. Comparison of Wound Infection in Skin Staples Versus Sutures for Skin Closure in Patients Undergoing Caesarean Section.J Soc Obstet Gynaecol Pak. 2019; Vol 9(4):221-225.

Introduction

Caesarean delivery is among the commonest major surgeries performed within the United States (U.S.) andglobally. Roughly 33% of pregnant females in the U.S. and 15 % globally are actually delivered through caesarean, yet this rate is increasing.[1] The incidence varies in different part of world from 3% to 21%.[2, 3] Because of these factors, caesarean incision complications including damage or infections at surgical site are a major source of morbidity after caesarean at significant cost for patients and healthcare system.[4]

Surgical site infection occurs in subcutaneous tissue or skin within the initial 30 days following a surgery. In addition, with purulent incisional drainage, there must

Authorship Contribution: [1] Substantial contribution to the conception or design of the work, [1-2] acquisition, [2-3] analysis, or interpretation of data for the work Final approval of the version to be published, [4-5] drafting the work or revising it critically for important intellectual content

Funding Source: none

Conflict of Interest: none

Received: April 28, 2019

Accepted: Dec 11, 2019

be species isolated from the culture obtained aseptically, or visible discomfort, localized swelling, heat or redness. Risk factors that contribute to SSI include the type of uterine incisions and skin, prolongedprocedural duration, greater than expected blood loss, failure of rigorous hemostasis, surgeon's specific skills (such as tissue processing) and patient-related factors including maternal BMI, the existence of comorbidities like anemia, hypertension, diabetes, previous uterine surgery, and pre-operative diagnosedchorioamnionitis.[4]

Another factor contributing to SSI is a type of suture material used for skin incision. Following C-section (CS), several suturing materials as well as skin staples (SS) are utilized to close the skin. A few of such suturing products were correlated with cost- effectiveness, lower rates of wound infection, enhancedcosmetic benefits, and lower discomfort. SS is simpler to employ and is correlated with a 3- to 4-fold decline inskin closure time with minimal wound infections. Although these are much more costly than suturing products, besides, SS is claimed to be more painful, resulting in a lower cosmetic effect.[5]

Most research on suturing formulations and SS for post-caesarean skin closure are targeted to superficial aspects, post-operative pain control, and patient satisfaction with contradictory results. [6]

Mackeen AD and others[7] evaluated the impact of skin closure procedures and materials following C-sectionon operative and maternal results and reported that today no clear evidence is present as for the ideal skin closure procedure following C-section.[7]

The rationale of the study is that conflicting results are recorded regarding wound infection in patients undergoing caesarean section and skin closure done either with sutures or skin staples and no local study is done to address this issue.

The study was conducted to establish the frequency of wound infection in skin closure of patients, done either with staples or sutures.

Methodology

The randomized control trial study was conducted in the Department of Obstetrics & Gynaecology, Benazir Bhutto Hospital, Rawalpindi from 4th February 2015 to 3rd September 2015. Non-probability: Convenience Sampling Technique was used. 654 cases, the sample

size is calculated by using WHO sample size calculatorfor two proportions

- P_1 = 4.9%
- P_2 = 10%
- Power of study=80%
- Level of significance=5%
- Sample size=654 (327 in each group)

Inclusion criteria:

- Age between 18-40 years.
- All women undergoing caesarean section
- Gestational age ≥36 weeks

Exclusion criteria:

- History of wound infection in any previous surgery
- Obese women (BMI > 30 Kg/ m^2)
- History of co-morbid condition (Diabetes mellitus, anemia)

Overall, 654 subjects fulfilling the criteria for inclusion/exclusion were enrolled from the Department of Obstetrics & Gynaecology, Benazir Bhutto Hospital, Rawalpindi. A well-versed pre-consent was taken from the participants to collect data for the study. Approval certificate has been obtained from hospital ethical committee. History, physical examination anddemographic information of all the patients wererecorded. Patients were divided into two groups by random-numbers table generated on computer. GroupA was allotted for Skin Staples and Group-B for sutures(prolene≠ 2-0 straight needle/ Silk 1 round body needle). Caesarean section was performed following the departmental protocols and skin closure was done according to randomization. Wound infection was recorded based on the presence of any of the following,purulent drainage, cellulitis (a bacterial infection beneath the skin marked by pain, swelling, warmth, andredness), abscess (an inflamed site in the body tissue with accumulated pus) or wound demanding debridement, drainage, and antibiotics linked with the infection's clinical diagnosis on 7th postoperative day.

SPSS version 16 was utilized for data entry and analysis. Mean and standard deviations were considered for quantitative variables including age, gestational age of the patients. Frequency and percentage calculations were performed for any qualitative variable including wound infection in both groups. Chi square test was applied to compare frequency of infection between both groups.

Stratification for age was recorded to address the effectmodifiers.

Results

In this study mean age of patients was 29.61 ± 4.36 years with minimum and maximum age 20 years and38 years respectively. Mean age in skin staples and sutures group was statistically same. Mean gestational age these females was 38.51 ± 0.64 with minimum and maximum gestational age 37 and 40 weeks. In both groups mean gestational age was same statistically. (Table I)

Table I: Comparison of age (years) and gestational age (weeks) in both groups

	Study groups		*P-value*
	Skin staples	Sutures	
Age (years)	29.64±4.17	29.58±4.54	0.851
Gestational age (weeks)	38.48±0.65	38.57±0.62	0.067

In skin staples group 53(16.2%) females underwent elective c-section and 274(83.8%) females underwent emergency c-section. In sutures group 63(19.3%)cases underwent elective and 264(80.7%) cases had emergency c-section, p-value = 0.306 (Table II).

Table II: Comparison of types of C section in both study groups

		Study Group		*Total*
		Skin staples	***Sutures***	
Type of C section	**Elective**	53 (16.2%)	63 (19.3%)	116 17.7%
	Emergency	274 83.8%	264 80.7%	538 82.3%
Total		327	327	654
		100.0%	100.0%	100.0%
p-value = 0.306				

In skin staples group 40(12.2%) patients developed wound infection and in sutures group 19(5.8%) femalesgot wound infection within 7th post operative day. Statically wound infection was significantly lower in suture groups as compared to staples groups, p-value = 0.04. **Table III.**

On stratifying data we found significant association between study groups and wound infection in patients aged ≥ 30 years, p-value = 0.005. (Table IV)

Table III: Comparison of wound infection in both study groups

		Study group		**Total**
		Skin staples	**Sutures**	
Wound infection at 7th day	***Yes***	40	19	59
		12.2%	5.8%	9.0%
	No	287	308	595
		87.8%	94.2%	91.0%
Total		327	327	654
		100.0%	100.0%	100.0%
p-value = 0.04				

Discussion

Caesarean section or C-section is an oldest and widely performed surgery on women in all over the world [8] witha low chance of mortality for mother and child. Recently, the Caesarean Section (CS) rates have been reported to increase globally, both in underdeveloped and developed nations.[9] All abdominal surgeries involve the risk of complications.[8] The frequency of c- section has increased significantly because of several feto-maternal factors.[10] Post-caesarean wound infections in surgical incisions are the bacterial infections. Following an abdominal (c-section) delivery, this infection may arise. The infection arises in around 3%-6% of females with c-section delivery. Wound

Table IV: Comparison of wound infection in both study groups with respect to age groups

Age groups			***Study Group***		***Total***	***p-value***
			Skin staples	***Sutures***		
< 30 years	***Wound infection At 7th day***	***Yes***	15	10	***25***	***0.161***
			10.3%	6.5%	***8.3%***	
		No	131	145	***276***	
			89.7%	93.5%	***91.7%***	

≥ 30 years	***Wound infection at 7th day***	***Yes***	25	9	***34***	***0.005***
			13.8%	5.2%	***9.6%***	
		No	156	163	***319***	
			86.2%	94.8%	***90.4%***	

infections elevate maternal morbidity, stay in the hospital, and medical expenses following a CS. The wound infection rates following CS published in the current literature varies between 3% and 16%, depending on surveillance approaches employed to distinguish infections, the population of patients, and the prophylactic antibiotics utilized.[11]

The technique of skin closure is becoming progressively significant in orthopedic surgical procedures with the advent of rapid healing as well as the demands placed upon surgeons to minimize periods of hospital stay.[12,13] Accelerated skin recovery and a suitable cosmetic outcome are the basic objectives of excellent wound closure, along with minimizing the risks for complications including wound infection or dehiscence.[13] For skin closurefollowing CS, a range of suturing materials as well as SS are utilized. A few of these suturing products are linked with lesser rates of wound infection, cost-effectiveness, enhanced cosmetic benefits, and lower discomfort.[14] These complications impose a significant effect on the patient's rehabilitation, resulting in greater morbidity, additional costs, delayed discharge, andlower satisfaction.[13] There is likewise a relationship between deep (prosthetic) infections and skin surface wound infections.[15]

Nylon sutures or metal staples are the most widely used approaches for skin closure following the orthopedic surgical procedure.[12] All strategies help to keep the surfaces of the skin attached when healing is taking place. Metal staples are claimed to be superior because they are considered faster and simpler in comparison to sutures.[16] Some researchers indicated that the application of metal clips or staples presents a higher risk for infection with the wound as well as may be less cosmetically suitable in comparison to sutures. [3]Metal staples could as well be further expensive.[12]

A study reported among 1100 females was assigned randomly into 3 groups: polyglycolic acid (PGA) suture group (N=361), skin staple (SS) group (N=373) andnylon suture group (N=366).[14] One more study reportedthat SSI was developed among 80 (11.2%) cases, 57 (71%) of then were detected via surveillance after discharge. Risk factors correlated with infections were analyzed. The subcuticular suture selection instead of staples for surgical site closure was correlated with a significantly lesser occurrence of infections (p-*value* = 0.021).[17]

Basha SL et al reported average rates of aggregate wound complications and wound isolation were 15.10%& 10.30% respectively. Wound separation took place considerably more frequently among staple cases compare with suture groups (17% vs 5%; p-value < 0.001), similar to composite wound complications (22% vs. 9%; p-value <0.001).[18] Another study reported Mackeen AD and workers[19] recorded infection in 10.6%in staples and 4.9% in the suture group. In this study 746 women were included, 370 to suture and 376 to staple closure. The adjusted odds ratio [OR] was 0.43, 95% confidence interval [CL] 0.23-0.78 respectively. [19] We in this study found in skin staples group 40(12.2%) patients developed wound infection and in sutures group 19(5.8%) females got wound infection within 7th post operative day. Statically wound infection was significantly lower in suture groups as compared to staples groups, p-value = 0.04. Our findings are similar to Basha et al[18] and Mackeen AD and workers[7] but are comparable to Johnson A et al[17]

There are other several factors related to wound infection, so a study reported 83.4% of females faced emergency LSCS, however, others were operated electively. Emergency LSCS inclines further to SSI thanthe elective surgical procedure. [20] In the current study in skin staples group 53(16.2%) females underwent emergency c-section and 274(83.8%) females underwent elective c-section. In sutures group63(19.3%) cases underwent emergency and 264(80.7%) cases had elective c-section, p-value = 0.306. Of the 121 infected cases, 80.16 % underwent an emergency procedure. The membranes might have ruptured during an emergency c-section, or home delivery might have been tried. Any earlier complication or condition or elevated exogenous bacterial infection or failures in sterile procedure or absence of prompt antibiotic prophylaxis may also occur. Martens et al. disclosed similar results as well.[21]

A meta analysis in 2015 also favored sutures closure method i.e. Females with suture-closed incisions were considerably less expected to undergo complications ofthe wound as compared to those with staples (risk ratio, 0.49; 95% confidence interval [CI], 0.28-0.87).Even though complications of the wound were stratifiedvia obesity, this variance persisted significantly. The reduction in wound-associated complications were large because of lower occurrence of suture- closed wound separations (risk ratio, 0.29; 95 percent CI, 0.20-0.43), as no significant variance was found in readmission, seroma, hematoma, or infection.[22]

Moreover, BMI of >25 affects the surgical outcomes.[23,24] Local improvements including reduced adipose tissue, a necessity for greater incision, reducedfat tissue circulation, and elevated retraction-related local tissue injury lead to elevated SSI occurrence among these subjects. These patients are disturbed by independent factors associated with homeostatic body equilibrium that occurs in wound restoration and immunity response. In this study, an improved BMI regarding an elevated infection rate was found to affect the procedure's outcome. We did not compare infectionrates in both groups concerning BMI but On stratifying data we found a significant association between study groups and wound infection in patients aged ≥ 30 years, p-value = 0.005. As in the current study mean age in skin staples and sutures group was statistically same, 29.64 ± 4.17 years and 29.58 ± 4.54 years, p- value = 0.851. The mean gestational age of these females was 38.51 ± 0.64 with minimum and maximum gestational age 37 and 40 weeks.

Conclusion

It is concluded that wound infection was significantly lower in suture groups as compared to staples groups.

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