



Evaluation of a strict protocol approach in managing women with severe disease due to abortion

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Aim. To evaluate whether the introduction of a strict protocol approach based on the systemic evaluation of critically ill pregnant women with complications of abortion affected outcome.

Setting. Indigent South Africans managed in the regional and tertiary hospitals of the Pretoria Academic Complex.

Method. Since 1997 a standard definition of severe acute maternal morbidity (SAMM) has been used in the Pretoria Academic Complex. All cases of SAMM and maternal deaths were entered on the Maternal Morbidity and Mortality Audit System programme. A comparison of outcome of severely ill women who had complications of abortion was made between 1997 - 1998 (original protocol) and 2002 - 2004 (strict protocol).

Outcome measures. The mortality index and prevalence of organ system failure or dysfunction.

Results. In 1997 - 1998 there were 43 women with SAMM who survived and a further 10 maternal deaths due to complications

of abortion, compared with 107 women with SAMM and 7 maternal deaths during 2002 - 2004. The mortality index declined from 18.9% in 1997 - 1998 to 6.1% in 2002 - 2004 ($p = 0.02$, odds ratio 0.28, 95% confidence limits 0.10 - 0.79). Significantly more women had hypovolaemic shock in 2002 - 2004 compared with 1997 - 1998 (54.4% v. 35.8%, $p = 0.04$), but fewer women had immune system failure including septic shock (18.4% v. 47.2%, $p = 0.0002$) and metabolic dysfunction (0 v. 5.7%, $p = 0.03$) and there was a trend to less renal failure (10.5% v. 22.6%, $p = 0.06$) and cardiac failure (4.4% v. 13.2%, $p = 0.08$).

Conclusion. The strict protocol approach based on systemic evaluation in managing critically ill pregnant women with complications of abortion, coupled with an intensive, regular feedback mechanism, has been associated with a reduction in the mortality index.

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Complications due to abortion are an important direct cause of maternal death in South Africa,^{1,2} being responsible for about 10% of direct deaths. This was also the fourth most common cause of acute severe morbidity in a survey of three clearly defined geographical areas in South Africa.³ The final and contributory causes of deaths were most commonly septic shock (56%), followed by renal failure, disseminated intravascular coagulation (DIC), respiratory and cardiac failure, all at about 10%.^{1,2} The major avoidable factor reported was lack of recognition of the severity of an abortion, leading to delay and under-treatment of the condition.^{1,2} Any improvement in the outcome of critically ill pregnant women with complications due to abortion would have to address ways to recognise organ system dysfunction/failure early and to prevent these organ systems from failing.

In 1997 the Pretoria Academic Complex initiated the use of a standard definition of severe acute maternal morbidity (SAMM)⁴ and has been collecting the data routinely ever

since. After the initial survey (1997 - 1998), protocols were reviewed and a new approach to managing critically ill pregnant women was introduced. This system was based on the routine systematic evaluation of each patient's organ systems. Detection of an abnormality served as a trigger to further investigate and support that organ system.⁵ This policy was adapted for managing critically ill pregnant women with specific common conditions and as a group became known as the strict protocols.

The implementation of new policies can be difficult to achieve.⁶ The change in policy was effected by regular reinforcement at daily audit meetings at the individual hospitals and weekly departmental meetings where the management of women with SAMM and all maternal deaths were a permanent agenda item. New trainees were exposed to the protocols immediately on starting and were given the relevant documents, and face-to-face meetings were held when problems occurred. Special training sessions were introduced to stress specific points. Finally, a report was presented to the provincial administration with specific recommendations specific to the region. There has been regular contact since.

This study looks at the effect of introduction of this strict protocol on the outcome of critically ill pregnant women with complications of abortion and identifies where further research or change in policy is required.

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Methods

The Pretoria Academic Complex consists of two academic hospitals (Pretoria Academic and Kalafong) and two sub-district hospitals (Mamelodi Day and Pretoria West). The area also receives referrals from other areas within Gauteng and the surrounding provinces. These women were excluded from the study. The population served is mainly an indigent general South African population.

The criteria for women with SAMM have been defined by Mantel *et al.*⁴ A woman with organ system dysfunction or failure would usually die if inadequate or no treatment or support was given. The criteria are based on clinical evaluation and specific investigations and are available at all regional or secondary hospitals and higher levels. Gestational trophoblastic disease is traditionally included as a complication of abortion and acute severe complications have also been included in this report.

Data on women with SAMM and maternal deaths were collected every morning at the respective hospitals. A 'near-miss' form was completed for each woman with SAMM and the maternal death notification form for all maternal deaths. Avoidable factors, missed opportunities and substandard care were listed and discussed at the meeting. The definitions used were the same as those in the confidential enquiries into maternal deaths.^{1,2} The data was entered on the Maternal Morbidity and Mortality Audit System (MaMMAS) database, developed by Johan Coetzee (Simply Software). The initial 2 years of the audit (1997 - 1998) were entered on the database. The initial project³ served as the platform for developing the database, and there were no missing data. The second time epoch, 2002 - 2004, was chosen because by then the strict protocol had been implemented and become established.

The mortality index was defined as the number of maternal deaths divided by the sum of women with SAMM and maternal deaths with abortion, and expressed as a percentage.⁷ The rates of each organ system dysfunction were compared between the two time periods.

Standard statistical techniques were used to compare the two time periods. The chi-square test was used to compare categorical data. A *p*-value of less than 0.05 was regarded as significant.

The strict management protocol used for critically ill pregnant women with complications of abortion was as follows.

1192 Stabilisation

All patients were stabilised after initial assessment. Shocked patients were resuscitated with the necessary fluid and blood therapy and oxygen was administered if necessary. Central lines were put up when indicated. Patients were catheterised and urine output was monitored. After stabilisation patients

were admitted to either the high-care unit or the intensive care unit.

Systemic evaluation

The following were performed and documented on all patients:

1. Central nervous system. Glasgow Coma Scale, orientation, pupil reactivity and limb reflexes.
2. Cardiovascular system. Pulse, blood pressure, heart sounds, and position of the apex beat.
3. Respiratory system. Respiratory rate, lung sounds and oxygen saturation. If the respiratory rate was increased, the oxygen saturation decreased or lung sounds were abnormal, arterial blood gas measurement and a chest X-ray was performed.
4. The hepatic system was evaluated by examining for jaundice and signs of liver tenderness, and measurement of the serum aspartate (AST) level. If there were signs of liver dysfunction, the patient's blood glucose level was monitored 4-hourly.
5. The renal system was evaluated by ensuring input and monitoring output carefully on a high-care chart.
6. Haematological system. Signs of a bleeding tendency (petechiae, echymoses and bleeding injection sites) were looked for on clinical examination. The haematocrit was measured and a platelet count performed. If the platelet count was low a clotting profile was done.
7. Endocrine system. The thyroid and breasts were evaluated for any lumps or tenderness and fingerprick glucose estimation was done.
8. Immunological system. The temperature was taken and examination for lymphadenopathy and AIDS-defining conditions was conducted. Counselling for HIV testing was performed if the HIV result was unknown and the patient was in a stable condition and able to give informed consent.
9. The gastrointestinal tract was examined for tenderness and bowel sounds.
10. Musculoskeletal system. The limbs were examined for signs of deep-vein thrombosis, the neck and mouth for mobility and the spinal column for abnormalities so that anaesthetic risks could be assessed.

Uterine evaluation

Abdominal examination was done to determine: (i) uterine size and tenderness; (ii) signs of free fluid in the abdomen; and (iii) peritonism.

Speculum examination determined: (i) presence of necrotic cervical tissue; and (ii) cervical trauma suggestive of possible unsafe intervention or the appearance of necrotic cervical tissue.



Vaginal examination determined: (i) uterine tenderness and size; (ii) cervical dilatation of the internal os; (iii) the presence of products of conception; and (iv) foul-smelling products, discharge from the uterus or presence of pus.

The indications for hysterectomy were as follows:

1. Septic shock. These patients were regarded as 'too sick not to operate'. After initial resuscitation and stabilisation, informed consent was obtained for hysterectomy. Surgery was performed as soon as possible on the emergency theatre list.
2. Multi-organ dysfunction. Any patient in whom evaluation revealed more than one dysfunctional organ system was counselled towards hysterectomy.
3. Necrotic appearance of the cervix on speculum examination.
4. Pus in the abdomen detected via colpopuncture done at the time of evacuation.

Antibiotic management

All patients were commenced on the following combination of intravenous antibiotics as soon as possible after diagnosis and admission: (i) second-generation cephalosporin; (ii) metronidazole; and (iii) gentamycin.

Fluid management

After resuscitation patients were treated with Maintelyte 1 litre 8-hourly until they were able to tolerate oral fluids and a soft diet. Fluid therapy was managed by calculation of a fluid balance. If a central venous line had been inserted, it was also used to manage fluid therapy. Patients who did not need intensive care unit admission usually started oral fluids or a soft diet the day after surgery, provided bowel sounds were present.

The audit programme is registered with the Ethics Committee of the Faculty of Health Sciences, University of Pretoria.

Results

In 1997 - 1998 there were 43 women with SAMM who survived and a further 10 maternal deaths due to complications of abortion, compared with 107 women with SAMM and 7 maternal deaths during 2002 - 2004. The mortality index declined from 18.9% in 1997 - 1998 to 6.1% in 2002 - 2004 ($p = 0.02$, odds ratio 0.28, 95% confidence limits 0.10 - 0.79). In 1997 - 1998, 36 of these women were classified as having septic abortions and 15 as having trauma and there were 2 women with gestational trophoblastic disease. In 2002 - 2004, 97 women had septic abortions and 17 were classified as having trauma. Figs 1 and 2 illustrate the ages and parities in the different time periods. The small numbers make the data unstable; however, significantly more primiparous women had

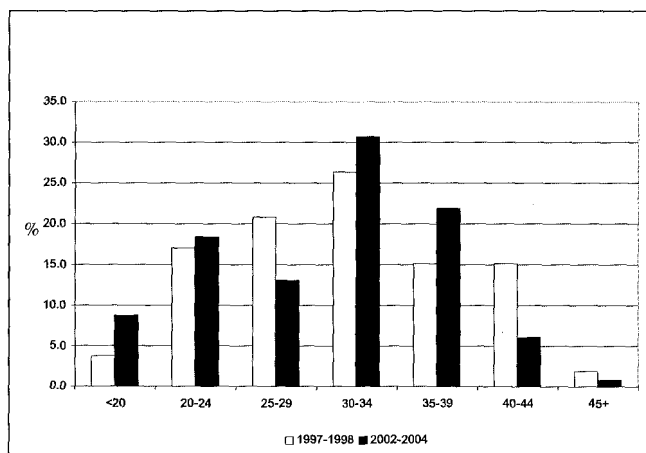


Fig. 1. Comparison of age distribution of women critically ill due to abortion between 1997 - 1998 and 2002 - 2004.

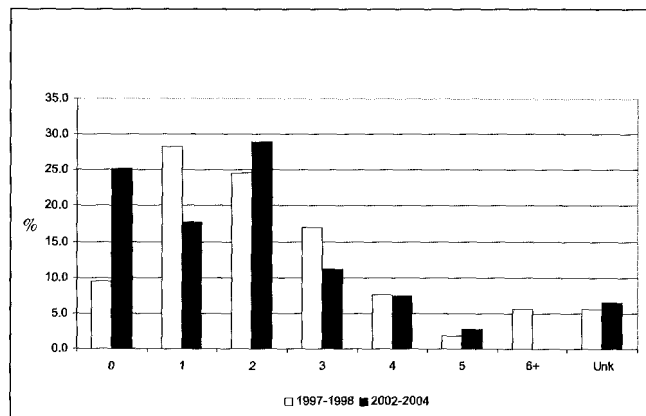


Fig. 2. Comparison of parity distribution of women critically ill due to abortion between 1997 - 1998 and 2002 - 2004.

complications in 2002 - 2004 (25.2%) than in 1997 - 1998 (9.4%) ($p = 0.03$).

Table I compares the organ system dysfunction/failure for women who were critically ill due to abortion in the two time periods. Significantly more women had hypovolaemic shock in 2002 - 2004 than in 1997 - 1998 (54.4% v. 35.8%, $p = 0.04$), but fewer women had immune system failure including septic shock (18.4% v. 47.2%, $p = 0.0002$) and metabolic dysfunction (0 v. 5.7%, $p = 0.03$). There was a trend to less renal failure (10.5% v. 22.6%, $p = 0.06$) and cardiac failure (4.4% v. 13.2%, $p = 0.08$). Patients with immune system failure were divided into two groups, namely those with septic shock (i.e. persistent hypotension despite adequate fluids in the presence of sepsis), and those with immune system failure due to AIDS. In women with abortion who are HIV infected there can be difficulties with separating septic shock and AIDS, so in this study to avoid bias women with septic shock and those with AIDS are grouped together in the category 'immune system failure'. In 1997 - 1998, 1 woman who died had AIDS and 4



Table I. Comparison of organ system dysfunction* between 1997 - 1998 and 2002 - 2004

	1997 - 1998				2002 - 2004				p-value
	SAMM	MD	SAMM + MD	% OSD	SAMM	MD	SAMM + MD	% OSD	
Hypovolaemic shock	17	2	19	35.8	62	0	62	54.4	0.04
Respiratory failure	4	4	8	15.1	12	3	15	13.2	0.92
Cardiac failure	3	4	7	13.2	5	0	5	4.4	0.08
Renal failure	8	4	12	22.6	12	0	12	10.5	0.06
Liver failure	0	0	0	0.0	5	0	5	4.4	0.18
Cerebral complications	0	1	1	1.9	1	1	2	1.8	1.0
Metabolic dysfunction	1	2	3	5.7	0	0	0	0	0.03
Haematological dysfunction	7	3	10	18.9	16	0	16	14.0	0.56
Immune system failure	22	3	25	47.2	17	4	21	18.4	0.0002
Total	43	10	53	100.0	107	7	114	100.0	0.02

*A patient can have more than one organ system failure/dysfunction.
SAMM = severe acute maternal morbidity; MD = maternal death; OSD = organ system dysfunction.

Table II. Comparison of avoidable factors, missed opportunities and substandard care

Factor	1997 - 1998		2002 - 2004	
	MD	SAMM	MD	SAMM
Patient orientated				
Delay in seeking help	4/10	13/39	2/7	42/107
Unsafe abortion	4/10	11/39	2/7	32/107
Administrative factors				
Lack of health care facilities including ICU beds [‡]	7/10	8/43	-	7/107
Barriers to entry	1/10	-	-	1/107
Communication problems	3/10	2/43	-	2/107
Medical personnel				
Inadequate initial assessment and problem list [†]	3/10	7/43	-	13/107
Incorrect diagnosis	1/10	1/43	-	6/107
Substandard management [‡]	8/10	11/43	-	12/107
Inadequate monitoring	1/10	3/43	-	-
Inadequate resuscitation	3/10	4/43	-	14/107

Denominators change where no information was available.
[‡]p = 0.0001.
[†]p = 0.28.
[†]p = 0.0001.
 SAMM = severe acute maternal morbidity; MD = maternal death.

others were HIV infected; 13 women (24.5%) were tested for HIV. In 2002 - 2004, 4 women who died and a further 8 who survived had AIDS. Another 11 were HIV infected. Thirty-six women (31.6%) were tested for HIV. Sixteen women had hysterectomies (30.2%) in 1997 - 1998 compared with 43 (37.7%) in 2002 - 2004. The difference was not statistically significant.

The average number of organ systems reported as dysfunctional or failing was 1.60 per case in 1997 - 1998 compared with 1.21 in 2002 - 2004.

Table II compares the avoidable factors, missed opportunities and substandard care for maternal deaths and SAMM in 1997 - 1998 and 2002 - 2004. Unsafe abortions occurred in 30.6% of

cases in 1997 - 1998 and 29.8% in 2002 - 2004. Delay in seeking medical attention was the most common patient-related avoidable factor, being recorded in 34.7% of cases in 1997 - 1998 and 38.6% in 2002 - 2004. Lack of facilities was recorded as an avoidable factor significantly less frequently in 2002 - 2004 (6.1%) than 1997 - 1998 (28.3%). Lack of available intensive care beds was the most common reason for lack of facilities being recorded in both time periods. This reduction in this avoidable factor occurred despite no actual increase in intensive care beds in the region, and indicates that fewer women required intensive care admission. A reduction in substandard management was also recorded, the figure falling from 35.8% in 1997 - 1998 to 10.5% in 2002 - 2004 ($p = 0.0001$).



Discussion

This review of managing critically ill pregnant women with complications of abortion between two time periods 5 years apart has shown a reduction in the mortality index and a change in pattern of organ system dysfunction/failure. Significantly fewer women are developing immune system failure than in the earlier time period. This occurred despite the increasing prevalence of HIV infection in the community. Significantly more women with miscarriages are having hypovolaemic shock.

There are three possible explanations for the change, namely earlier identification of patients, better management, and the impact of the Choice of Termination of Pregnancy Act.

The change has been associated with the introduction of and adherence to a strict protocol for managing critically ill women with complications of abortion. The strict protocol was based on the 1997 - 1998 audit. The strict protocol has enabled us to identify critically ill women more accurately and timeously, resulting in a reduction in the average number of cases of organ system dysfunction or failure in 2002 - 2004 without a corresponding increase in the number of women having a hysterectomy. The strict protocol, with its set indications for hysterectomy, may also enable us to identify the appropriate patients to undergo the procedure. The reduction in the rate of substandard management from 35.8% to 10.5%, although this is subjective, gives further support to improvement in care as an explanation. Early recognition of complications and early evacuation of the uterus and aggressive antibiotic cover, coupled with vigilance regarding further complications, appears to have led to fewer severe complications, as evidenced by the 25% reduction in the average number of organ systems reported as dysfunctional or failing per critically ill woman in the 2002 - 2004 cohort. The feedback system employed, of regular audit meetings to discuss cases, one-on-one meetings where required and regular teaching sessions to discuss specific issues, complies with successful intervention in previous randomised trials.⁶ Regular staff changes necessitate very active reinforcement of protocols.

The promotion of the Choice on Termination of Pregnancy Act may have encouraged women to attend earlier, thereby allowing clinicians more time to prevent further complications. There has been a massive decline in the number of spontaneous abortions, with a concomitant increase in the number of terminations of pregnancy, in the area.⁸ This shift has coincided with a reduction in maternal mortality due to abortion but not in the prevalence of critically ill women.⁸ This lack of reduction in women critically ill but a significant reduction in maternal deaths would suggest better identification and management of these women rather than being a direct consequence of the freer availability of TOP services. The increase in prevalence of hypovolaemic shock may be the result of increased illegal use of misoprostol,

as suggested by Jewkes *et al.*⁹ It is possible that the shift to misoprostol for illegal abortions has resulted in 'safer' illegal abortions and a resultant reduction in sepsis, but an increase in haemorrhage.

It is disturbing that a significant proportion of women were still having unsafe abortions in 2002 - 2004. Jewkes *et al.*¹⁰ found that the main reason for not using legal services were not knowing the law, knowing the law but not knowing where to go to have an abortion, anticipation of rudeness of staff, and being afraid of being found out. Surprisingly, being too late in pregnancy or finding too long a waiting list were factors in only 7% of women not using legal services. Women's willingness to self-medicate and visit traditional healers in these circumstances may influence the overall ability of the new legislation to reduce abortion mortality.¹⁰ Mhlanga¹¹ reported that there are still barriers to access to termination of pregnancy services in many parts of the country; as a result women become frustrated by the delays and deliberate obstruction. Women would then access misoprostol to initiate abortion and present to the hospital with vaginal bleeding. The increase in the prevalence of women who were critically ill due to excessive bleeding might well indicate increasing use of misoprostol.

Conclusion

The strict protocol approach based on the systemic evaluation of severely ill women in with complications of abortion has resulted in early identification of cases of acute maternal morbidity and a reduction in the mortality index.

We thank all the registrars for diligently completing the 'near miss' forms.

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