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Comparison of Different Management Strategies for First-Trimester Miscarriages in the Sri Lankan Population

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Abstract

Background: Miscarriage, defined as the spontaneous loss of pregnancy before the fetus reaches viability, is the most common complication in early pregnancy. Traditional surgical evacuation methods, though effective, pose risks such as infection, bleeding, and increased costs. In order to minimize surgical complications, newer treatment strategies like expectant management (watchful waiting) and medical management are introduced. Although these newer methods offer potential benefits, they lack comparative evaluation regarding safety and efficacy, especially in the Sri Lankan context, creating a research gap. **Methodology:** A cross-sectional analytical study was conducted in teaching hospitals in Sri Lanka, involving 160 women with uncomplicated first-trimester miscarriages divided equally into medical and expectant management groups to compare each management strategy's success rate and complications. High-risk categories like septic abortions or severe hemorrhage were excluded. The study adopted a non-probability convenient sampling technique. Data were collected using an interviewer-administered data collection form at discharge and 14-day follow-up. Statistical analysis was performed using SPSS, employing chi-square and t-tests to compare success rates and complications. **Results:** Medical management showed a significantly higher success rate (83.8%) compared to expectant management (62.5%, $p < 0.05$), achieving complete removal of products of conception. Two groups had significant differences in the period of amenorrhea, degree of products, fetal pole length, and size of gestational sac ($p < 0.05$). Additional medical treatments, hospital admissions, and PV bleeding were higher in the expectant group compared to the medical group ($p < 0.05$). Difficulty in micturition (8.8% vs. 1.3%) and fever (7.5% vs. 2.5%) were significantly higher in the med-

ical management group compared to the expectant management group ($p < 0.05$). **Conclusion:** Medical management using misoprostol is a highly effective and acceptable alternative to surgical intervention for first-trimester miscarriages in Sri Lanka, outperforming expectant management in success rates and reduced complications. These findings advocate revising clinical guidelines and increasing awareness of non-surgical options to ensure patient-centered, cost-effective care. Further research is recommended to evaluate long-term outcomes and integrate patient preferences into management protocols.

Keywords

Miscarriage, Expectant Management, Medical Management, Cross-Sectional Study, First Trimester

1. Introduction

1.1. Background

Miscarriage is by far the most common complication occurring in early pregnancy. It is estimated that 10% - 15% of all clinically detected pregnancies are ended in that way [1] [2], affecting patients' medical, psychological, and social health. It is estimated that one-third of women experience miscarriages at some time in their life.

Miscarriage is defined as a spontaneous loss of pregnancy before the fetus reaches viability. The definition of viability can vary depending on the region and availability of the facilities. In Sri Lankan standards, we take 24 weeks for the maturity, after which the fetus can survive on its own outside the mother's womb. WHO definition is the expulsion of a fetus or embryo 500 g or less with a gestational limit of less than 22 weeks [3]. Most miscarriages occur before twelve weeks of gestation and are called "early miscarriages". Those that happen afterward are called "late miscarriages". There are many types of miscarriages. Early pregnancy failures are diagnosed when the clinical examination shows closed cervical os and, in ultrasound, confirmed gestational sac > 25 mm with no fetal pole or fetal pole > 7 mm with no fetal cardiac activity. Diagnosis of Incomplete miscarriage is made when there is a history of the passage of clots and tissue particles with opened cervical os, and transvaginal ultrasound confirmed heterogeneous material within the uterine cavity with endometrial thickness of more than 15mm. When the endometrial thickness is < 15 mm with an empty uterine cavity, it is called a complete miscarriage [4] [5].

Historically, they are associated with significant maternal morbidity and mortality, although maternal deaths due to miscarriages are rare thanks to standards of medical care. Management options for miscarriage have significantly evolved in the recent past. Diagnosis of miscarriage is traditionally followed up by surgical evacuation due to the fear of infections and bleeding. However, the surgical evacuation of products of conception has its complications, such as the risk of anes-

thesia, cervical lacerations, hemorrhage, uterine perforation, pelvic infection, and very rarely, it can result in bowel or bladder injury, broad ligament hematoma, secondary subfertility, and Asherman's syndrome [6] [7]. Also, it increases hospital stay and the cost to both the patient and the hospital.

In order to minimize surgical complications, hospital stays, and costs, newer treatment strategies came into the picture in the form of expectant management (watchful waiting) and medical management with prostaglandin analogs and antiprogesterones. Drawbacks of these treatment modalities include failure to achieve complete miscarriage, infections, bleeding, and recurrent hospital admissions. This study compares the efficacy and patient acceptance of these two methods.

According to nice guidelines, all women who are diagnosed with a miscarriage should be offered expectant management for 7 - 14 days as the first-line management strategy. Other management options should be explored if the women are at increased risk of hemorrhage or increased risk from the effects of hemorrhage, evidence of infection, and previous traumatic experiences associated with pregnancy.

It has been found that the attending specialist's recommendation primarily affects patient preferences for the treatment option [4]. However, women should be allowed and encouraged to choose the management modality according to their preference, and this has been shown to have the best health-related quality of life [8]. Improved access to early pregnancy assessment units and greater awareness among women have led to increasing demand for more conservative management of incomplete miscarriage [6]. Up to 70% of women have been found to prefer expectant care if given the choice [4] [9].

Although several randomized trials have compared surgical and medical treatment [10]-[12], surgical and expectant treatment [9] [13], and medical and expectant treatment [14], evidence on the safety and efficacy of these treatment options is still lacking [15]. This is mainly due to the comparatively small number of women being treated, protocol variations, and inconsistent outcomes assessment. Hence, the optimal management option for the two commonest types of miscarriage, incomplete miscarriage and early pregnancy failure, is still uncertain [15] [16].

A randomized control trial was done at St Mary's Hospital London, using up to two doses of 600 mg misoprostol intravaginally with follow-up for 1 week, which reduced the need for ERPC by 90% when compared with expectant management in early pregnancy failures; RR = 0.1 (95% CI, 0.04 ± 0.28) [17]. Also, it shows no difference between either modality when managing incomplete miscarriages. Another study was done by the Department of Reproductive Health and Research, The WHO, which also showed no statistically different results when comparing medical management with expectant care [18].

MIST trial conducted by J. Trinder highlighted the fact that the rate of infection is not different between all three modalities of miscarriage management (surgical, expectant, medical) and remains reassuringly low as 2% - 3% [19]. Studies regard-

ing medical management of miscarriage in Sri Lanka are almost nonexistent as prostaglandin analogs like misoprostol were not licensed to use until very recently. In Sri Lanka, most women with incomplete and missed miscarriages have a routine ERPC. While most patients are unaware of expectant care and medical management, doctors and other medical staff have poor knowledge. However, in two recent studies in the North Colombo Teaching Hospital and Sri Jayawardhanapura Teaching Hospital, expectant care was found to be a safe and effective alternative to ERPC [8].

The current study was designed to observe whether expectant care or medical management is feasible and acceptable in women attending Teaching Hospitals in Sri Lanka and whether it could significantly reduce the need for surgical evacuation in women with uncomplicated incomplete and missed miscarriages without increasing any adverse effects. The standard method of doing medical management is the administration of oral mifepristone (progesterone antagonist), followed up by the insertion of vaginal misoprostol. For incomplete miscarriage, 600 micrograms and for early pregnancy failures, 800 micrograms of misoprostol are inserted into the posterior fornix.

As mifepristone is expensive and less available, 600 micrograms per vaginal misoprostol were used for both incomplete miscarriages, and 800 micrograms were used for missed miscarriages in medical management.

1.2. Unique Health Infrastructure of Sri Lanka

Sri Lanka's healthcare infrastructure is well-suited for research on miscarriage management due to its extensive teaching hospital network and standardized care protocols. The current study was conducted at the National Hospital Colombo and Colombo North Teaching Hospital, major tertiary care centers with advanced diagnostic and therapeutic facilities. These hospitals play a pivotal role in providing specialized obstetric care, including the management of first-trimester miscarriages through surgical, medical, and expectant approaches. Their status as teaching hospitals allows for integrating clinical research with patient care, ensuring that evidence-based practices are followed. Furthermore, the availability of skilled medical personnel and free access to essential medications supports comprehensive miscarriage management and allows for evaluating different treatment modalities in a real-world clinical setting.

1.3. Justification

Miscarriage is one of the most common complications in early pregnancy, affecting a significant proportion of women and their physical, psychological, and social well-being. Current management in Sri Lanka predominantly involves surgical evacuation (ERPC), which, while effective, is associated with risks such as uterine perforation, infections, anesthesia-related complications, and increased healthcare costs. Alternatives such as expectant and medical management using prostaglandin analogs like misoprostol have demonstrated efficacy and safety in international studies.

However, data specific to the Sri Lankan population is limited, particularly regarding these methods' feasibility, success rates, and patient acceptance. Additionally, a lack of awareness among healthcare providers and patients further limits the adoption of these alternatives. This study aims to address this knowledge gap by rigorously comparing the outcomes of medical and expectant management in first-trimester miscarriages, focusing on success rates, adverse effects, and patient satisfaction. The findings will provide evidence to optimize management protocols, reduce the dependency on surgical methods, and align clinical practices with international standards while considering local resource constraints and patient preferences.

2. Literature Review

The literature review was performed using databases like PubMed, Google Scholar, Cochrane, and Science Direct, using keywords like "miscarriage", "expectant management", "medical management", and "first trimester". Most studies were conducted in developed countries, with limited research from South Asia and local settings.

Management of miscarriage was assessed by using a randomized controlled trial design in 2006 in the United Kingdom. The objective of that study was to ascertain whether a clinically important difference exists in the incidence of gynecological infection between surgical management and expectant or medical management of miscarriage. The study was conducted in early pregnancy assessment units of seven hospitals in the United Kingdom. Women of less than 13 weeks gestation, with a diagnosis of early fetal demise or incomplete miscarriage, were taken for the study. Two interventions were applied to the two experimental groups of eligible study participants: medical and surgical management. One group of patients with early fetal demise were given a vaginal dose of misoprostol before the surgical evacuation. Confirmed gynecological infection at 14 days and eight weeks was observed as outcome measures. One thousand two hundred women were recruited for the study (399 to expectant management, 398 to medical management, and 403 to surgical management). No differences were found in the incidence of confirmed infection within 14 days between the expectant group (3%) and the surgical group (3%) (Risk difference 0.2%, 95% confidence interval 2.2% to 2.7%) or between the medical group (2%) and the surgical group (0.7%, 1.6% to 3.1%). Compared with the surgical group, unplanned hospital admissions were significantly higher in both the expectant group (risk difference 41%, 47% to 36%) and the medical group (10%, 15% to 6%). Similarly, compared with the surgical group, the number of women with an unplanned surgical curettage was significantly higher in the expectant group (risk difference 39%, 44% to 34%) and the medical group (30%, 35% to 25%). Ultimately, the study concluded that the incidence of gynecological infection after surgical, expectant, and medical management of first-trimester miscarriage is low (2% - 3%), and no evidence exists of a difference in the method of management. However, significantly more unplanned admissions and

surgical curettage occurred after expectant and medical management than after surgical management [9].

Another randomized controlled study was conducted to compare vaginal misoprostol versus expectant treatment in women presenting with spontaneous miscarriage. Sixty women presenting with spontaneous miscarriage were recruited to the study at the Queen Mary Hospital between 1998 and 1999. They were randomized to Group 1: misoprostol and Group 2: expectant management. Women in the misoprostol group received vaginal misoprostol 400μg on days 1, 3 and 5. The expectant group was followed up according to the same schedule. Suction evacuation was performed if there was excessive bleeding or abdominal pain or if a gestational sac was detected by transvaginal scan on day 15. Fifty-nine women completed the trial. Those who did not require suction evacuation up to the time of the return of normal menstruation were considered to be successful. The incidence of side effects was comparable between the two groups. Three women in the expectant group and one in the misoprostol group underwent emergency suction evacuation because of excessive bleeding. The mean duration of vaginal bleeding was similar for both groups (14.6 days in the misoprostol group versus 15.0 days in the expectant group). The successful rate in the misoprostol group was significantly higher than that of the expectant group (83.3 versus 48.3%, $P < 0.05$). After the results of the study, the investigators recommended that repeated vaginal misoprostol 400μg given on days 1, 3, and 5 as a treatment option for women with first-trimester spontaneous miscarriage [4].

Bagratee 2004 (a randomized controlled trial) compared the efficacy of expectant vs medical management of first-trimester miscarriage. It showed 88.5% (n = 46) overall success for medical management versus 44.2% (n = 23) for expectant management. The need for surgical intervention was significantly lower in the medical management group (11.5%) compared to 55.8% in the expectant group. Bagratee 2004 also performed a subgroup analysis comparing the effects of medical vs. expectant management in incomplete miscarriage vs. early pregnancy failure, where significant success with medical management was observed in the early pregnancy failure group but not in the incomplete miscarriage group. Additionally, the rapid completion of miscarriage within two days was higher in their medical group (73.1%) compared to 13.5% in the expectant group, improving patient satisfaction. The study reported increased hospital visits associated with expectant management. The side effect profiles were statistically insignificant in both groups [14].

The MIST trial, a multicenter randomized controlled study, compared the outcomes of surgical, medical, and expectant management for miscarriage, involving 1200 participants across three groups. It reported similar low infection rates (2 - 3%) across all methods within 14 days. However, when compared to the surgical group, the number of women who had unplanned surgical curettage was significantly higher in the expectant group (risk difference 39%, 44% to 34%) and medical group (risk difference 30%, 35% to 25%). The trial emphasized a higher suc-

cess rate with surgical management than with medical and expectant management [19].

MisoREST trial (a cohort study) compared surgical vs expectant management in women with incomplete uterine evacuation after misoprostol treatment for miscarriage, where curettage achieved a 95% (n = 62) success rate compared to 85% (n = 112) for expectant management, highlighting a relative risk (RR) of 1.1 (95% CI 1.03 - 1.2) for successful outcomes. The Miso REST trial provides valuable insights emphasizing the need to tailor the management according to the degree of retained products (completely vs incompletely retained) [20].

Ghosh 2021 explored methods for managing early miscarriage using a network meta-analysis. Surgical methods, such as suction aspiration dilatation and curettage, were more effective than medical methods (e.g., mifepristone plus misoprostol) and expectant management or placebo in achieving complete miscarriage. Medical methods rank next, while expectant management shows the lowest effectiveness and highest risk of complications, such as unplanned surgeries or infections. However, subgroup analysis indicates surgical and medical interventions are particularly beneficial for women with missed miscarriages, compared to incomplete miscarriages where natural progression may occur more readily [21].

A randomized controlled trial conducted at North Colombo Teaching Hospital assessed the efficacy of expectant versus surgical management of incomplete miscarriage before 14 weeks of amenorrhea. It reported a treatment success rate of 90.1% at one week and 94.4% at two weeks for expectant management, compared to 95.7% for surgical treatment. Expectant management showed no cases of infection, whereas one case occurred in the surgical group. Hospital stays were significantly shorter in the expectant group (1.58 days versus 2.57 days, $p = 0.008$). Both groups experienced minimal hemoglobin drop (0.72 g/dL in the expectant group and 0.91 g/dL in the surgical group, $p = 0.0003$) [8].

Another randomized controlled trial conducted at Teaching Hospital Mahamodara, Galle, evaluated the efficacy of surgical vs expectant management of incomplete miscarriage. It found that 69% of cases managed expectantly achieved complete expulsion within one week, increasing to 84% by two weeks, with only three patients requiring surgical intervention. In the surgical group, one patient needed a repeat procedure. Although vaginal bleeding lasted longer in the expectant group ($p < 0.01$), the duration of pain and days off work were comparable across groups. Rare complications, such as infection and uterine perforation, occurred at similar rates between groups. Both methods' satisfaction rates were equally high (97.5%) [22].

3. Objectives

3.1. General Objective

To compare the efficacy of medical and expectant management of first-trimester miscarriages.

3.2. Specific Objectives

(1) To compare the Success rate of management procedures for first-trimester miscarriages among the study population. The success rate was calculated by evaluating how many surgical evacuations were needed in medical and expectant groups.

(2) To compare the incidence rate of severe hemorrhage following different management procedures in first-trimester miscarriages. Significant blood loss was evaluated by measuring pre-post-procedure hemoglobin counts. If the drop of Hemoglobin is > 1 g/dl, it is considered a significant blood loss.

(3) To compare the incidence rate of infections following different management procedures in the first trimester. Infection, in this case, is endometritis in the setting of miscarriages. If the patient presented with evidence of infection like fever, abdominal pain, or vaginal discharges with high inflammatory markers (C reactive proteins, white cell count) with or without positive microbial cultures (blood or high vaginal), it was considered endometritis.

4. Methodology

4.1. Study Design

Cross-sectional analytical study design.

4.2. Study Setting

The study was conducted in selected teaching hospitals in Sri Lanka (National Hospital Colombo and Colombo North Teaching Hospital).

4.3. Target Population

Patients who were admitted to a teaching hospital in Sri Lanka following a first-trimester miscarriage

Inclusion Criteria:

(1) Patients who presented with uncomplicated miscarriage.

(2) Period of amenorrhea less than 12 weeks.

Exclusion criteria:

(1) Evidence of infections and severe bleeding, which require urgent surgical evacuation.

(2) High risk of significant blood loss (Anemia, Coagulation disorders, hemoglobinopathies).

(In the above two scenarios, medical and expectant management is inappropriate, and immediate surgical evacuation is recommended considering the patient's safety).

(3) Contraindications for prostaglandin—Uncontrolled Asthma and hypertension, glaucoma, mitral stenosis, known allergy to prostaglandin.

(4) Inability to understand and give consent.

4.4. Sample Size Calculation

P_1 = Expected proportion of variables in Intervention group = 80%;

P_2 = Expected proportion of variables in controls = 95%;

α = 0.05;

β = 0.2;

K = constant, which is a function of α and β;

N = Sample size.

$$N = \frac{KP_1(1-P_1)+P_2(1-P_2)}{(P_1-P_2)^2}$$

$$= \frac{7.9\times(0.95\times0.05)+(0.8\times0.2)}{(0.95-0.8)^2}$$

$$= \frac{7.9\times(0.0475+0.16)}{0.0225}$$

$$N = 73(cases = 73,\ Controls = 73)$$

Considering a 10% non-response rate, the sample size calculated for each group was 80.

4.5. Sampling Technique

A non-probability convenient sampling technique was applied to sample selection.

4.6. Study Instrument

An interviewer-administered a data collection sheet (structured as a Google form) consisting of 6 parts related to identifying patient-related information and management strategies.

Part 1. Socio-demographic information;

Part 2. Information related to previous pregnancies;

Part 3. Information regarding present pregnancy—presenting complaint and findings elicited;

Part 4. Condition at the time of discharge;

Part 5. Condition at 14 days after discharge;

Part 6. Outcome—completely cured, admitted due to complications, treated on an outpatient basis, needed surgical evacuation.

Reliability Checking and Validation of Data Collection Instruments

The primary instrument used in this research was an interviewer-administered data collection form structured as a Google Form. Ensuring the validity and reliability of the data collection instruments was crucial to maintaining the integrity of the study's findings. Validity checks included content validity, face validity, and construct validity. Reliability checks included internal consistency, test-retest reliability, inter-rater reliability, and pilot testing. A detailed reliability checking and validation of study instruments is given as an Appendix.

4.7. Procedure of Data Collection

Details regarding managing miscarriage were recorded using a Google form de-

veloped and shared with all medical officers in gynecology units in selected teaching hospitals in Sri Lanka. One person from each teaching unit was identified as a focal point. Google form was filled at the time of discharge, and the D14 review following discharge. This data collection procedure was conducted until the required minimum sample size was completed.

4.8. Statistical Analysis

All collected data was entered into an Excel 2019 datasheet. Then, it was converted into an SPSS spreadsheet. Data analysis was facilitated by SPSS version 25.0. All continuous scale data was described using measures of central tendencies. All categorical data was described by using frequencies and percentages. The categorical comparison was conducted appropriately using the z-test for proportion and the chi-square test. A ratio scale data comparison was done using the student t-test. Associations were determined by using the Odds ratio. 95% confidence interval and the 0.05 probability cut-off were applied to determine statistical significance. Multivariate regression analysis was conducted to control for potential confounding factors.

4.9. Dissemination of Findings

Research findings will be disseminated by submitting them to reputed journals for publication and submitting the dissertation to PGIM. Knowledge translation can be done by educating others about findings so they can be implemented into clinical practice.

4.10. Administrative Clearance

Permission to conduct the study was obtained from the director of the institution and the relevant consultant in charge of the respective treatment units.

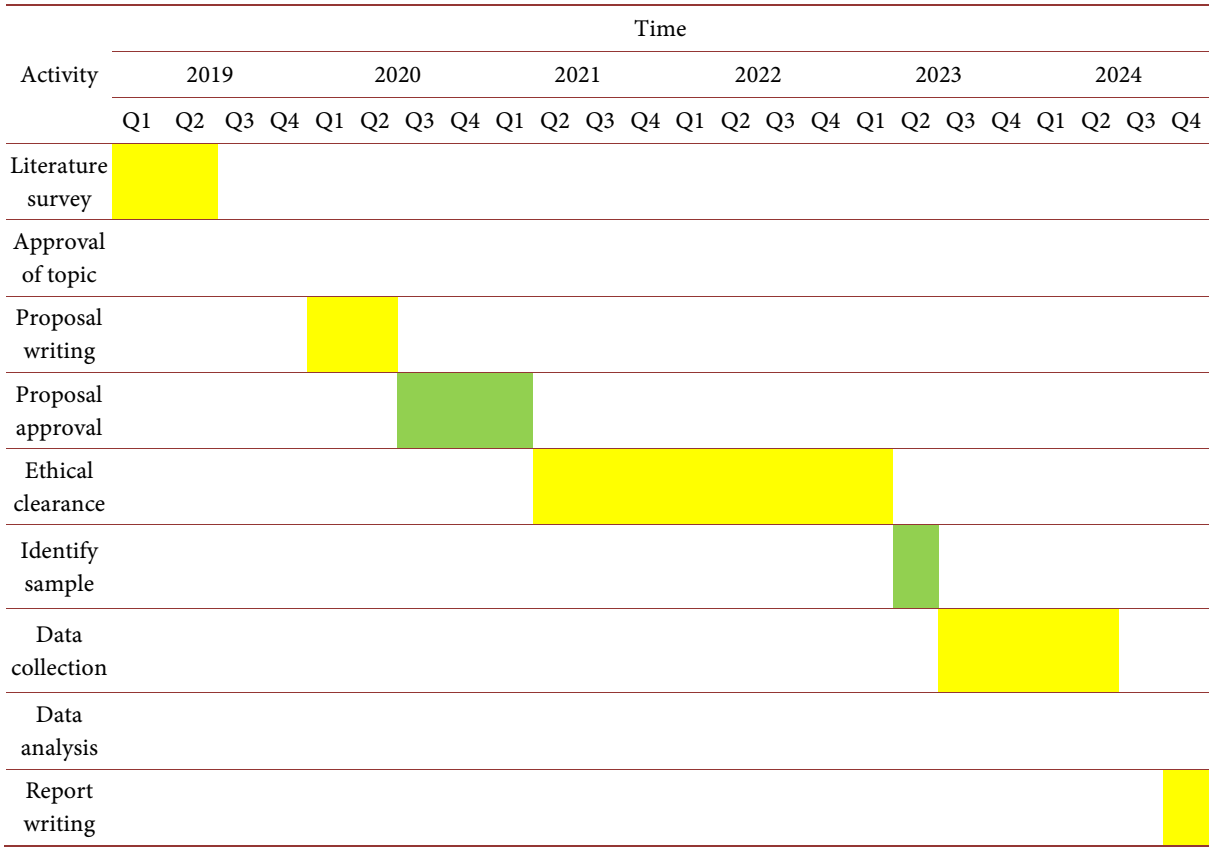
4.11. Ethical Considerations

Ethical clearance was obtained from the Ethics Review Committee Post Graduate Institute of Medicine of the University of Colombo. The approved study protocol was registered in the Sri Lanka clinical trial registry before conducting the data collection process.

Before getting their consent, all the participants enrolled in this study were given an information sheet in their most convenient language (Sinhala, Tamil, or English). They were free to withdraw from the study at any point. Contact details of researchers were made available to participants. Data collection and counseling were done by the researcher or trained competent medical officers who appreciate the sensitive mental condition following a pregnancy loss, as well as the confidentiality of patients was well guarded. The reputed guidelines accepted both treatment modalities [4]. To further reduce the vulnerability of the research participants, it was thoroughly explained that not agreeing to participate in the study did not bring them any form of ill-treatment or mismanagement. If there was a lan-

guage barrier when educating the minority patients, a translator was used. Confidentiality was maintained by storing the data securely. Collected data are kept in a password-protected computer for one year. After one year, data will be deleted, and papers will be burnt.

4.12. Schedule/Duration



Q—Quartile.

5. Results

5.1. Socio-Demographic Characteristics

This study includes data from 160 participants, with 80 participants in each expectant and medical management group.

Table 1 presents the socio-demographic characteristics of participants. Most participants in both groups were housewives, accounting for 51.2% in the expectant management group and 43.8% in the medical management group. The proportions of laborers, non-executive workers, executives, and professionals were similar between groups. Most participants had schooling up to O/L or A/L levels (42.5% and 38.8%, respectively, in the expectant group and 40% and 37.5% in the medical group). Ethnicity distribution was also comparable, with the majority being Sinhala (77.5% expectant and 76.3% medical). No significant differences were found across all variables ($p > 0.05$).

Table 1. Analysis of socio-demographic characteristics.

Socio-demographic information		Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
		Expectant n (%)	Medical n (%)				
Occupation	Housewife	41 (51.2%)	35 (43.8%)	3.235	4	0.519	0.142
	Laborer	6 (7.5%)	7 (8.8%)				
	Non-executive	27 (33.8%)	28 (35%)				
	Executive	5 (6.3%)	5 (6.3%)				
	Professional	1 (1.3%)	5 (6.3%)				
Education	No schooling	1 (1.3%)	1 (1.3%)	0.370	4	0.985	0.048
	Up to grade 5	4 (5%)	5 (6.3%)				
	Up to O/L	34 (42.5%)	32 (40%)				
	Up to A/L	31 (38.8%)	30 (37.5%)				
	Graduated	10 (12.5%)	12 (15%)				
Ethnicity	Sinhala	62 (77.5%)	61 (76.3%)	0.075	2	0.963	0.022
	Tamil	7 (8.8%)	8 (10%)				
	Muslim	11 (13.8%)	11 (13.8%)				
	Other	0	0				
Religion	Buddhist	58 (72.5%)	54 (67.5%)	2.114	3	0.549	0.115
	Hindu	7 (8.8%)	7 (8.8%)				
	Catholic	4 (5%)	9 (11.3%)				
	Islam	11 (13.8%)	10 (12.5%)				

Table 2 shows an independent samples t-test analysis for age and POA between the two groups. The mean age in the expectant group was 28.21 years (SD = 5.92) compared to 28.98 years (SD = 6.39) in the medical group, with no significant difference (p = 0.435). However, POA was significantly longer in the medical group (mean = 9.70 weeks, SD = 1.63) than in the expectant group (mean = 8.15 weeks, SD = 1.33; p = 0.000).

Table 2. Independent samples T-test analysis of age and POA.

Variable	Management	N	Mean	SD	Mean Difference	t	df	p value
Age (Years)	Expectant	80	28.21	5.919	−0.763	−0.783	158	0.435
	Medical	80	28.98	6.396				
POA (weeks)	Expectant	80	8.15	1.338	−0.1550	−6.468	158	0.000
	Medical	80	9.70	1.634				

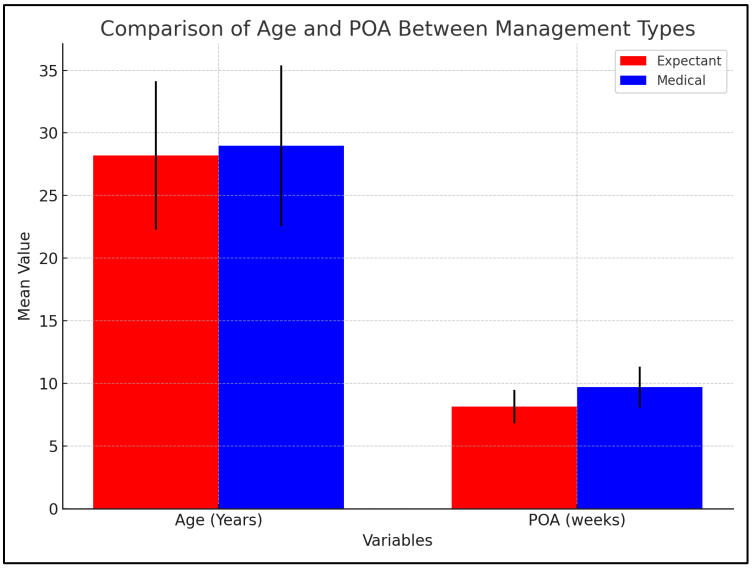


Figure 1. Comparison of age and POA between management types.

Figure 1 illustrates the comparison of age and POA between the two groups. The mean age was 28.21 years in the expectant group (SD = 5.92) and 28.98 years in the medical group (SD = 6.39), showing no significant difference ($p = 0.435$). However, POA differed significantly between groups, with the medical group having a higher mean of 9.70 weeks (SD = 1.63) compared to 8.15 weeks (SD = 1.33) in the expectant group ($p < 0.001$).

Multivariate Regression Analysis Controlling Potential Confounding Factors

The multivariate logistic regression analysis assessed factors influencing the success of miscarriage management. The model had a Pseudo R^2 of 0.069, explaining approximately 7% of the variability in treatment success. The log-likelihood was −83.722, and the LLR's p value was 0.051, indicating the model was close to statistical significance. Among the predictors, management type (medical vs. expectant) was a significant factor ($\beta = 0.8645$, $p = 0.026$), showing that medical management had higher success rates. Hemoglobin levels showed a marginal trend ($\beta = -0.2870$, $p = 0.096$), suggesting lower levels might reduce success. Other factors, including age, period of amenorrhea, degree of retained products, and gestational sac size, were not significant predictors ($p > 0.05$). These findings highlight that medical management significantly improves success rates, while other clinical characteristics did not show substantial predictive value in this model.

5.2. Information Related to Previous Pregnancies

Table 3 analyzes previous pregnancy details. The mean number of live births was 1.10 (SD = 1.14) in the expectant group and 1.31 (SD = 1.14) in the medical group. Both groups had identical mean values for intrauterine deaths (0.05, SD = 0.22). The mean number of previous abortions was slightly higher in the medical group (0.49, SD = 0.78) compared to the expectant group (0.35, SD = 0.57). No statisti-

cally significant differences were found for these variables ($p > 0.05$).

Table 3. Analysis of information related to previous pregnancies.

Variable	Management	N	Mean	SD	Mean Difference	t	df	p value
Live birth	Expectant	80	1.10	1.143	-0.212	−1.176	158	0.241
	Medical	80	1.31	1.143				
IUD	Expectant	80	0.05	0.219	0.000	0.000	158	1.000
	Medical	80	0.05	0.219				
Abortion	Expectant	80	0.35	0.576	-0.137	−1.269	158	0.206
	Medical	80	0.49	0.779				

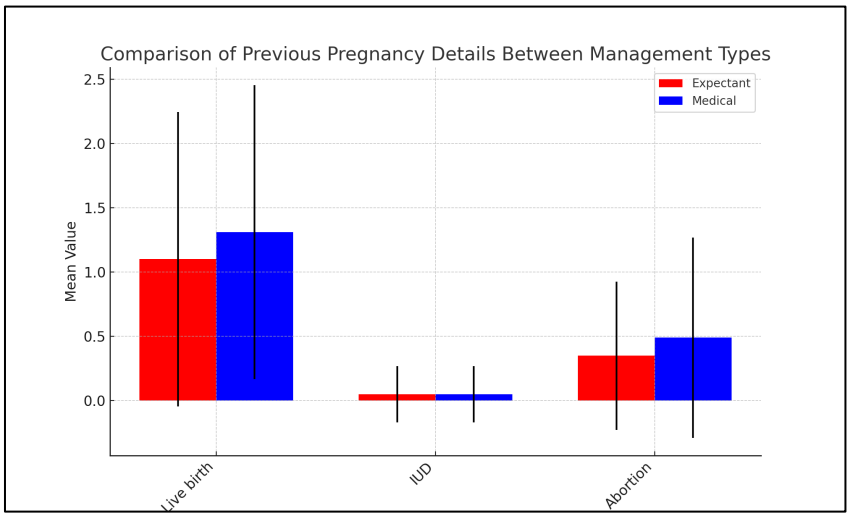


Figure 2. Comparison of previous pregnancy details between management types.

Figure 2 illustrates the comparison of previous pregnancy details, showing no significant differences in live births, IUDs, or abortions between the management types.

5.3. Presenting Complaint

Table 4 highlights presenting complaints. Vaginal bleeding was reported by 56.3% in the expectant group and 60% in the medical group, while abdominal pain was reported by 6.3% and 3.8%, respectively. There were no significant differences between the two groups ($p > 0.05$), and none of the participants presented with fever.

Table 4. Analysis of presenting complaint.

Presenting complaint	Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
	Expectant n (%)	Medical n (%)				
Vaginal bleeding	45 (56.3%)	48 (60%)	0.231	1	0.631	0.038

Continued

Abdominal pain	5 (6.3%)	3 (3.8%)	0.526	1	0.468	0.057
Fever	0	0	No statistics were computed as the variable is a constant			

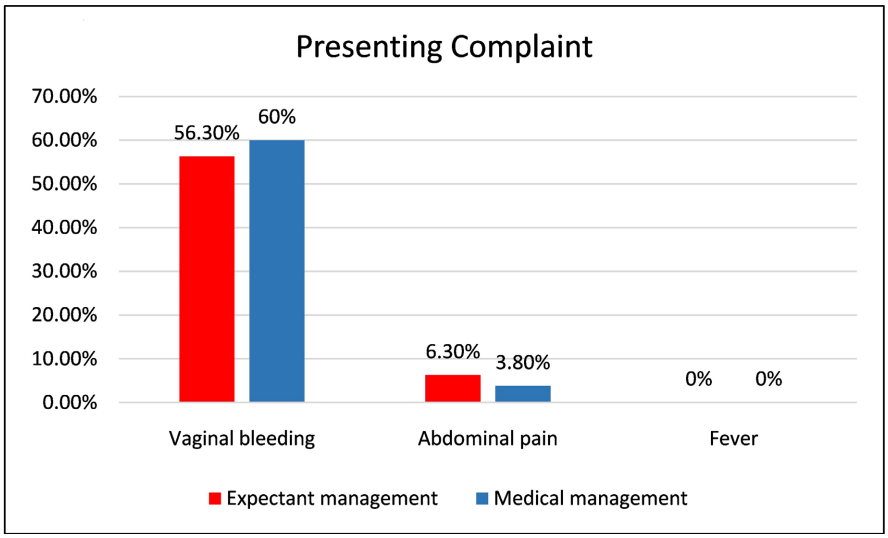


Figure 3. Comparison of presenting complaints.

Figure 3 compares the complaints presented by the two groups. The distribution of vaginal bleeding and abdominal pain is similar, with no statistically significant differences. Fever was recorded in none of the participants.

5.4. Findings at the Initial Presentation

Table 5. Analysis of findings elicited during the examination.

Findings elicited	Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
	Expectant n (%)	Medical n (%)				
Anemia	0	0				
Internal bleeding	0	0	No statistics computed as variables are constants			
Infections	0	0				

Table 5 shows that none of the participants in either group had anemia, internal bleeding, or features of infection at the initial presentation, suggesting a lower baseline risk level in all participants.

Table 6 provides findings from ultrasound examinations at the initial presentation. The mean degree of products was significantly lower in the expectant group (24.80 mm, SD = 7.57) compared to the medical group (28.88 mm, SD = 9.72; p = 0.031). Similarly, fetal pole and gestational sac measurements were smaller in the expectant group (mean fetal pole: 8.15 mm, SD = 1.39 vs 10.20 mm, SD = 3.45; p = 0.021; mean gestational sac: 26.93 mm, SD = 1.91 vs 29.83 mm, SD

= 2.57; p = 0.001). Hb levels were similar between groups, with a mean of 12.00 g/dL (SD = 0.83) in the expectant group and 11.85 g/dL (SD = 1.15) in the medical group (p = 0.345).

Table 6. Analysis of findings elicited during USS examination and Hb level.

Variable	Management	N	Mean	SD	Mean Difference	t	df	p value
Degree of products (mm)	Expectant	45	24.80	7.567	−4.081	−2.193	85	0.031
	Medical	42	28.88	9.721				
Fetal pole (mm)	Expectant	20	8.15	1.387	−2.050	−2.420	33	0.021
	Medical	15	10.20	3.448				
Gestational sac (mm)	Expectant	15	26.93	1.907	−2.893	−3.733	36	0.001
	Medical	23	29.83	2.570				
Hb	Expectant	80	12.00	0.827	0.150	0.948	158	0.345
	Medical	80	11.85	1.148				

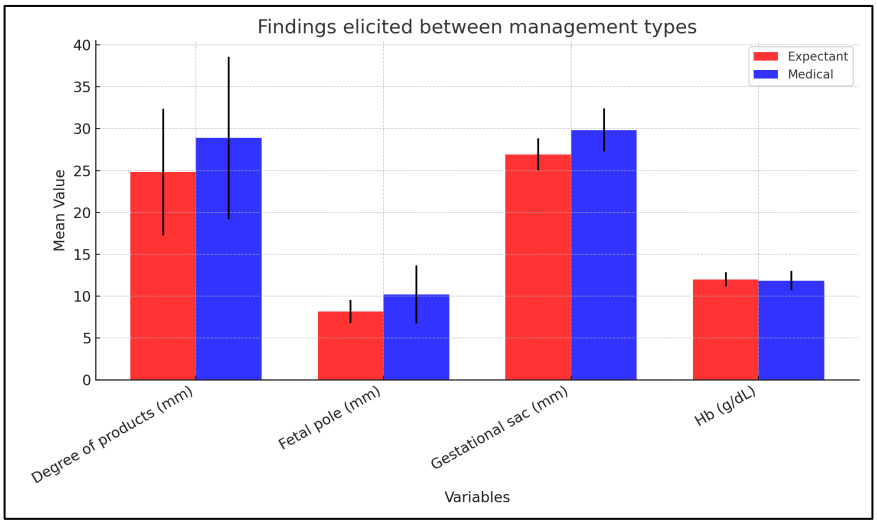


Figure 4. Comparison of findings elicited during USS examination and Hb level between management types.

Figure 4 compares ultrasound findings and Hb levels between groups. The expectant management group had smaller mean values for gestational sac and fetal pole measurements than the medical management group. Significant group differences were observed in all the other three variables except for Hb level.

5.5. Additional Pharmacological Management (Analgesic Usage)

Table 7 examines analgesic usage. In the expectant group, 93.8% did not require analgesics, compared to 78.8% in the medical group. PCM was used by 6.3% in the expectant group and 20% in the medical group, while a combination of PCM and diclofenac was used by 1.3% in the medical group. Significant differences were found in analgesic usage (p = 0.02) and dosage (p = 0.044).

Table 7. Analysis of analgesic usage.

Additional medications		Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
		Expectant n (%)	Medical n (%)				
Analgesic	None	75 (93.8%)	63 (78.8%)	7.805	2	0.02	0.221
	PCM	5 (6.3%)	16 (20%)				
	PCM & diclofenac	0	1 (1.3%)				
Doses	None	75 (93.8%)	63 (78.8%)	8.110	3	0.044	0.225
	PCM one dose	3 (3.8%)	12 (15%)				
	PCM three doses	2 (2.5%)	4 (5%)				
	PCM & diclofenac one dose	0	1 (1.3%)				

5.6. Findings at the Time of Discharge

Table 8 summarizes findings at discharge. Complete removal of products was achieved in 71.3% of the medical group, while all participants in the expectant group had retained products. Vaginal bleeding was present in 6.3% of the medical group and none in the expectant group. None of the participants had a fever on discharge. Other than fever, all the other findings were statistically significant ($p > 0.05$).

Table 8. Analysis of findings at the time of discharge.

Findings at discharge	Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
	Expectant n (%)	Medical n (%)				
All products removed	0	57 (71.3%)	88.544	1	0.000	0.744
Retaining products	80 (100%)	22 (27.5%)	90.980	1	0.000	0.754
Vaginal bleeding	0	5 (6.3%)	5.161	1	0.023	0.180
Fever	0	0	No statistics were computed as the variable is a constant			

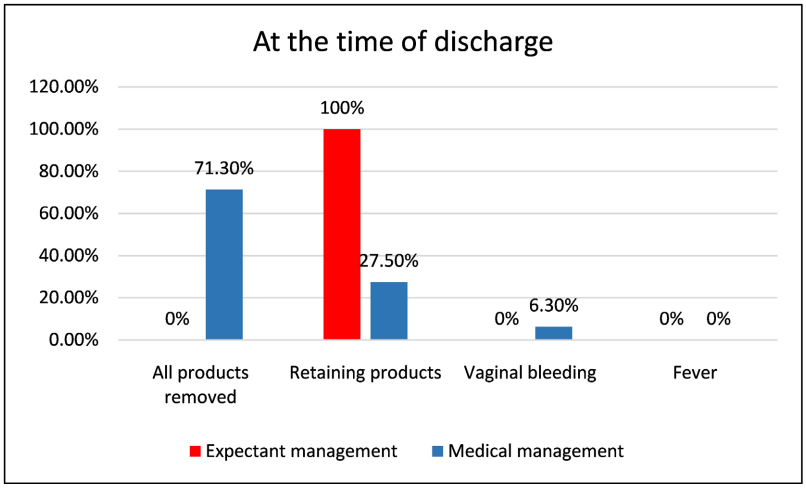


Figure 5. Comparison of findings at the discharge.

Figure 5 compares findings at discharge. However, except for fever, other findings were statistically significant.

5.7. Findings at D14

Table 9 presents findings on day 14. The medical management group demonstrated better outcomes, with a higher percentage of complete product removal (88.8% vs. 65%) and fewer retained products (10% vs. 35%, $p < 0.05$). Additional medical treatments, hospital admissions, and PV bleeding were higher in the expectant group compared to the medical group ($p < 0.05$). Difficulty in micturition (8.8% vs 1.3%) and fever (7.5% vs. 2.5%) were significantly higher in the medical management group compared to the expectant management group ($p < 0.05$).

Figure 6 compares findings at day 14, underscoring the superior efficacy of medical management in terms of complete product removal and reduced complications.

Table 9. Analysis of findings at D14.

Findings at D14	Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
	Expectant n (%)	Medical n (%)				
All products removed	52 (65%)	71 (88.8%)	12.692	1	0.000	0.282
Retaining products	28 (35%)	8 (10%)	14.337	1	0.000	0.299
PV bleeding	19 (23.8%)	6 (7.5%)	8.012	1	0.005	0.224
Fever	2 (2.5%)	6 (7.5%)	2.105	1	0.147	0.115
Additional medical treatment	29 (36.3%)	8 (10%)	15.504	1	0.000	0.311
Hospital admission	31 (38.8%)	8 (10%)	17.936	1	0.000	0.335
Difficulty in micturition	1 (1.3%)	7 (8.8%)	4.737	1	0.03	0.172

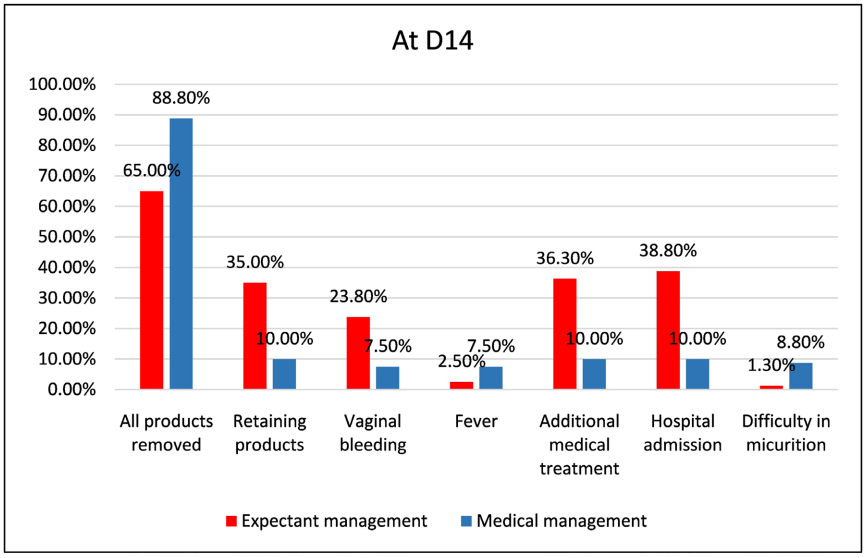


Figure 6. Comparison of findings at D14.

5.8. Outcome

Table 10. Analysis of the outcome

Outcome	Management		Pearson chi-square value	Degrees of freedom (df)	Asymptotic significance (p value)	Effect size (Crammer's V)
	Expectant n (%)	Medical n (%)				
Completely cured	50 (62.5%)	67 (83.8%)	9.191	1	0.002	0.240
Admitted due to complications	0	0				
Treated on an outpatient basis	0	0				
Needed surgical evacuation	30 (37.5%)	13 (16.3%)				

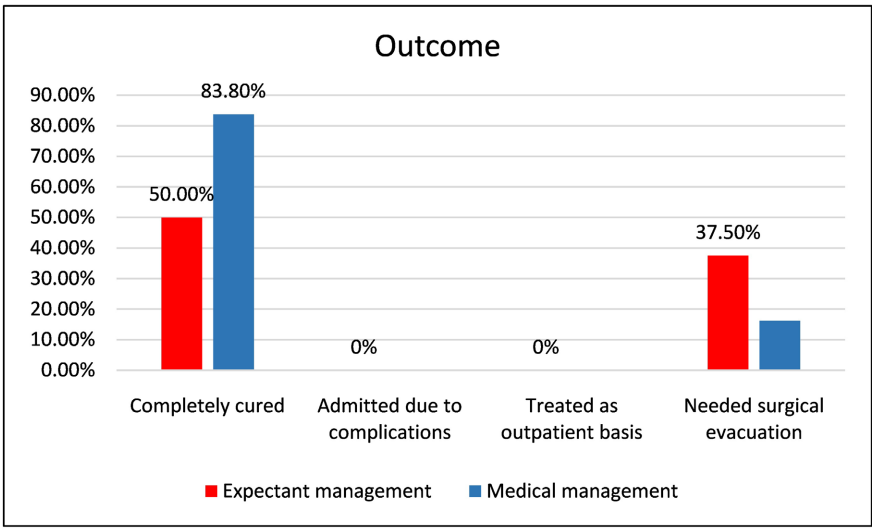


Figure 7. Comparison of outcomes between two management types.

Table 10 summarizes the success rates of expectant vs medical management. The success of the treatment is defined by achieving a complete cure and avoiding surgical evacuation. The success rate in the medical group [83.8% (n = 67)] was significantly higher compared to expectant group [62.5% (n = 50)] ($p < 0.05$). None of the participants reported additional admissions due to complications or the need for outpatient treatment.

Figure 7 compares the outcomes between management types, illustrating medical management' statistically higher success rate in achieving a complete cure.

6. Discussion

6.1. Summary of the Key Findings

The study included data from 160 participants, with 80 participants in each expectant and medical management group. The baseline characteristics of the participants showed no significant differences across the two groups ($p > 0.05$). However, POA was significantly longer in the medical group (mean = 9.70 weeks, SD

= 1.63) than in the expectant group (mean = 8.15 weeks, SD = 1.33; p = 0.000). The number of live births, IUDs, and abortions were statistically insignificant between the two groups. 56.3% (n = 45) in the expectant group and 60% (n = 48) in the medical group presented with vaginal bleeding, while 6.3% (n = 5) in the expectant group and 3.8% (n = 3) in the medical group complained of abdominal pain where there were no significant differences between the two groups ($p > 0.05$). None of the participants presented with a fever. None of the participants in either group had anemia, internal bleeding, or features of infection at the initial presentation. Initial USS examination revealed a significantly higher degree of products and fetal pole length in the expectant management group, while a significantly larger gestational sac was seen in the medical management group ($p < 0.05$).

At discharge, products were removed entirely in 71.3% (n = 57) of the medical group, while all participants in the expectant group had retained products. Vaginal bleeding was present in 6.3% (n = 5) of the medical group and none in the expectant group. None of the participants had a fever on discharge. Other than fever, all the other findings were statistically significant ($p > 0.05$). After analyzing the findings at D14, the medical management group demonstrated better outcomes, with a higher percentage of complete product removal (88.8% vs. 65%) and fewer retained products (10% vs. 35%, $p < 0.05$). Additional medical treatments, hospital admissions, and PV bleeding were higher in the expectant group compared to the medical group ($p < 0.05$). Difficulty in micturition (8.8% vs. 1.3%) and fever (7.5% vs. 2.5%) were significantly higher in the medical management group compared to the expectant management group ($p < 0.05$). The success rate in the medical group [83.8% (n = 67)] was significantly higher compared to the expectant group [62.5% (n = 50)] ($p < 0.05$), achieving complete removal of products of conception. 37.5% (n = 30) in the expectant management group and 16.3% (n=13) in the medical management group required surgical evacuation.

6.2. Evidence from the Clinical Practice Guidelines

The guideline evidence for miscarriage management is based on recommendations from major international health organizations, including the American College of Obstetricians and Gynecologists (ACOG), the National Institute for Health and Care Excellence (NICE), the Royal College of Obstetricians and Gynaecologists (RCOG), the International Federation of Gynecology and Obstetrics (FIGO), and the Association of the Scientific Medical Societies in Germany (AWMF). These guidelines outline three primary approaches: expectant management, medical management, and surgical management, each with specific indications, success rates, and potential risks [5] [7].

Expectant management involves allowing the pregnancy tissue to pass naturally without medical or surgical intervention. NICE recommends it as the first-line approach for 7 - 14 days without complications such as severe bleeding or infection. The success rate depends on the type of miscarriage: incomplete miscarriage

(91%), missed miscarriage (76%), and blighted ovum (66%). While it avoids medical or surgical intervention, expectant management carries risks of unpredictable bleeding, potential need for follow-up treatment (10% - 30% of cases), and, in rare instances, disseminated intravascular coagulation (DIC) if the fetal tissue remains for an extended period. Patients choosing this option must have regular follow-up to monitor for complete miscarriage [2] [7].

Medical management typically involves the administration of misoprostol, a prostaglandin E1 analog, which induces uterine contractions and cervical dilation to expel pregnancy tissue. Some guidelines, such as those from FIGO and ACOG, recommend pre-treatment with mifepristone (200 mg) 24 hours before misoprostol to improve effectiveness. The vaginal route of administration is preferred due to higher efficacy and fewer gastrointestinal side effects compared to oral administration. The success rate of medical management ranges from 81% to 95%, with incomplete miscarriage responding best (93% - 97%), followed by missed miscarriage (88%) and blighted ovum (81%). Side effects include pain, nausea, diarrhea, and heavy bleeding, with 1% of patients requiring blood transfusion. If miscarriage is incomplete, additional doses or surgical intervention may be needed [7] [16].

Surgical management is recommended in cases of infection, heavy bleeding, hemodynamic instability, or patient preference. The standard procedure is vacuum aspiration (suction curettage), which is more effective and safer than traditional sharp curettage. This method has a 97% - 98% success rate, with complications such as uterine perforation (< 0.1%), infection (< 1%), and repeat curettage (2% - 3%). Although surgical management provides immediate resolution and minimizes prolonged bleeding, rare long-term risks include Asherman's syndrome, incompetent cervix, and increased risk of placenta accreta spectrum disorders in future pregnancies [7] [15].

Treatment choice should be based on individual patient circumstances, preferences, and clinical indications. All guidelines emphasize informed consent, ensuring that patients understand the advantages and risks of each approach. Expectant and medical management can often be conducted on an outpatient basis, whereas surgical management typically requires hospital-based or ambulatory surgical care. The AWMF guideline differs slightly from international recommendations, as it limits medical management to pregnancies up to 9 weeks due to slightly lower success rates compared to surgical intervention [5] [7].

6.3. Comparison of the Study Findings with the International Studies

Bagratee 2004 (a randomized controlled trial) compared the efficacy of expectant vs medical management of first-trimester miscarriage. The current study reported a success rate of 83.8% (n = 67) for medical management compared to 62.5% (n = 50) for expectant management, while Bagratee 2004 showed a similar trend, with 88.5% (n = 46) overall success for medical management versus 44.2% (n = 23) for expectant management. The need for surgical intervention was significantly lower

in the medical management groups, with 16.3% in the current and 11.5% in the RCT, compared to 37.5% and 55.8% in the expectant groups, respectively. Bagratee 2004 also performed a subgroup analysis comparing the effects of medical vs. expectant management in incomplete miscarriage vs. early pregnancy failure, where significant success with medical management was observed in the early pregnancy failure group but not in the incomplete miscarriage group, highlighting the importance of individualized treatment strategies rather than a holistic approach. Additionally, the rapid completion of miscarriage within two days was higher in their medical group (73.1%) compared to 13.5% in the expectant group, improving patient satisfaction. Both studies reported increased hospital visits associated with expectant management. The side effect profiles were statistically insignificant in both groups [14].

The MIST trial, a multicenter randomized controlled study, compared the outcomes of surgical, medical, and expectant management for miscarriage, involving 1200 participants across three groups. It reported similar low infection rates (2% - 3%) across all methods within 14 days. However, when compared to the surgical group, the number of women who had unplanned surgical curettage was significantly higher in the expectant group (risk difference 39%, 44% to 34%) and medical group (risk difference 30%, 35% to 25%). The trial emphasized a higher success rate with surgical management than with medical and expectant management. However, the trial did not specify the outcomes according to the type of miscarriage. The findings from the present study showed that the medical management group achieved a higher success rate of complete product removal (83.8%) compared to the expectant group (62.5%), aligning partially with the MIST trial's observation that surgical interventions were more frequent in the expectant group [19].

MisoREST trial (a cohort study) compared surgical vs expectant management in women with incomplete uterine evacuation after misoprostol treatment for miscarriage, where curettage achieved a 95% (n = 62) success rate compared to 85% (n = 112) for expectant management, highlighting a relative risk (RR) of 1.1 (95% CI 1.03 - 1.2) for successful outcomes. Similarly, the present study revealed that medical management achieved an 83.8% success rate versus 62.5% for expectant management ($p < 0.05$), emphasizing the superiority of intervention over expectant management. However, the current study did not categorize the outcomes based on the type of miscarriage. Thus, in women with an incompletely evacuated uterus following misoprostol or spontaneous partial evacuation, expectant management is a safe and effective option. The MisoREST trial provides valuable insights emphasizing the need to tailor the management according to the degree of retained products (completely vs incompletely retained) [20].

6.4. Comparison of the Study Findings with the Local Studies

A randomized controlled trial conducted at North Colombo Teaching Hospital assessed the efficacy of expectant versus surgical management of incomplete mis-

carriage before 14 weeks of amenorrhea. It reported a treatment success rate of 90.1% at one week and 94.4% at two weeks for expectant management, compared to 95.7% for surgical treatment. Expectant management showed no cases of infection, whereas one case occurred in the surgical group. Hospital stays were significantly shorter in the expectant group (1.58 days versus 2.57 days, $p = 0.008$). Both groups experienced minimal hemoglobin drop (0.72 g/dL in the expectant group and 0.91 g/dL in the surgical group, $p = 0.0003$) [8]. Another randomized controlled trial conducted at Teaching Hospital Mahamodara, Galle, evaluated the efficacy of surgical vs expectant management of incomplete miscarriage. It found that 69% of cases managed expectantly achieved complete expulsion within one week, increasing to 84% by two weeks, with only three patients requiring surgical intervention. In the surgical group, one patient needed a repeat procedure. Although vaginal bleeding lasted longer in the expectant group ($p < 0.01$), the duration of pain and days off work were comparable across groups. Rare complications, such as infection and uterine perforation, occurred at similar rates between groups. Both methods' satisfaction rates were equally high (97.5%) [22]. Both studies concluded that expectant management is a safe and effective alternative in the management of incomplete miscarriage. However, we need additional evidence comparing the success rates of medical vs. expectant vs. surgical management options in incomplete miscarriage vs. silent/missed miscarriage to update treatment protocols.

Ghosh 2021 explored methods for managing early miscarriage using a network meta-analysis. Surgical methods, such as suction aspiration dilatation and curettage, were more effective than medical methods (e.g., mifepristone plus misoprostol) and expectant management or placebo in achieving complete miscarriage. Medical methods rank next, while expectant management shows the lowest effectiveness and highest risk of complications, such as unplanned surgeries or infections. However, subgroup analysis indicates surgical and medical interventions are particularly beneficial for women with missed miscarriages, compared to incomplete miscarriages where natural progression may occur more readily. Therefore, we must focus on factors predicting success, including the type of miscarriage, and tailor the management for each patient rather than adopting a gross approach that adheres to unit protocols [21].

6.5. An Overview of the Factors Predicting the Success of Expectant vs Medical Management

In addition to the type of miscarriage, there are multiple clinical, biochemical, and ultra-sonographic factors predicting the likelihood of complete resolution of a miscarriage through expectant vs medical vs surgical management. One of the key predictors includes the presence of active vaginal bleeding at presentation, which significantly increases the likelihood of spontaneous resolution during expectant management. Biochemical markers such as lower serum progesterone and β-human chorionic gonadotropin (β-hCG) levels have been associated with higher

success rates of both expectant and medical management [23]. Gestational age and sonographic findings, including gestational sac diameter and crown-rump length, are independent predictors of success of expectant management. Personalized treatment plans incorporating these variables may help counsel women with early miscarriage, improving patient outcomes [24]. In the present study, gestational age was significantly longer in the medical group (mean = 9.70 weeks, SD = 1.63) than in the expectant group (mean = 8.15 weeks, SD = 1.33; p = 0.000). Initial USS examination revealed a significantly higher degree of products and fetal pole length in the expectant management group, while a significantly larger gestational sac was seen in the medical management group ($p < 0.05$). These findings may have contributed to the differences in observed outcome measures and warrant further investigation in the future.

6.6. Women's Perceptions Regarding Miscarriage Management Strategies

Miscarriage is very sensitive and emotionally challenging for a woman. Patient-centered management strategies will help them to come out of the traumatic event. Therefore, we need to understand the women' perceptions of miscarriage management types, including personal preferences, complications, and recovery time [25]. Expectant management allows for the natural expulsion of the pregnancy tissue, which some women prefer for its non-invasive nature, although it may involve prolonged uncertainty and emotional distress. Medical management, often utilizing medications like misoprostol, is favored for its less invasive approach and lower cost than surgery. Despite being more invasive, surgical management, such as dilation and curettage, is valued for its definitive resolution and shorter recovery time [26]. Women should be counseled regarding the factors predicting the success of each management strategy, understand their perceptions, and be allowed to clarify misconceptions. The present study did not evaluate the effect of women's perceptions on selecting the type of management strategy and outcome measures.

6.7. Strengths and Limitations

This study significantly contributes to minimizing the research gap addressing the feasibility and outcomes of medical and expectant management in Sri Lanka. The inclusion of participants from multiple teaching hospitals enhances the study's generalizability. The rigorous statistical analysis and ethical adherence further strengthen the validity of the findings.

The study's reliance on a non-probability sampling technique and cross-sectional study design instead of a randomized controlled trial limits its ability to generalize findings to the broader Sri Lankan population. The absence of an evaluation of qualitative dimensions like emotional and psychological experiences, post-management quality of life, and women's satisfaction regarding miscarriage management is another limitation. The present study could have precisely analyzed the outcomes depending on the type of miscarriage and predictors of successful outcomes for each management strategy.

6.8. Recommendations

Increasing awareness among healthcare providers and patients about the efficacy and safety of medical and expectant management options is essential to bridge the knowledge gap and promote informed decision-making rather than relying heavily on surgical management. Research should be expanded in the form of randomized controlled trials concerning the type of miscarriage and predictors of success to validate these findings in larger, more diverse populations in the local setting. Patient preferences and socio-cultural factors also should be integrated into clinical decision-making processes.

7. Conclusion

This study underscores the potential for medical and expectant management strategies to provide practical, patient-centered care for first-trimester miscarriages in Sri Lanka. These findings challenge the over-reliance on surgical interventions, demonstrating superior success rates and reduced complications. A shift in clinical practice is required, supported by increased awareness, resource optimization, and further well-designed research, bridging the identified research gaps. Emphasizing patient preferences and offering comprehensive emotional support help align with global best practices, ensuring safer and more empathetic healthcare delivery for affected women.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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Appendix

Validation and Reliability Checks for Data Collection Instruments

Ensuring the validity and reliability of the data collection instruments was crucial to maintaining the integrity of the study's findings. The primary instrument used in this research was an interviewer-administered data collection form structured as a Google Form. The form consisted of six sections covering socio-demographic details, previous pregnancies, current pregnancy information, discharge conditions, follow-up conditions at 14 days, and overall outcomes. The following steps were undertaken to guarantee content, construct validity, and internal consistency.

Validity Checks

1) Content Validity:

The data collection form was developed based on an extensive literature review and guidelines from reputable sources, including the National Institute for Health and Care Excellence (NICE) and the World Health Organization (WHO). A panel of three obstetrics and gynecology experts, including senior consultants and academic researchers, reviewed the form for relevance, clarity, and comprehensiveness. Feedback was incorporated to ensure all essential variables were covered without ambiguity.

2) Face Validity:

The form underwent preliminary evaluation with five healthcare professionals not involved in the study to assess the questions' ease of understanding and clarity. Minor adjustments in wording were made based on their suggestions to enhance user-friendliness.

3) Construct Validity:

Questions were aligned with standard definitions and criteria for miscarriage management outcomes to confirm that the instrument effectively measured the intended constructs. Correlations between sections were analyzed during pilot testing to ensure logical coherence.

Reliability Checks

1) Internal Consistency:

Cronbach's alpha coefficient was calculated for multi-item sections (e.g., presenting complaints and outcome measures). An alpha value of 0.82 indicated good internal consistency, suggesting that the items within each section reliably measured the same construct.

2) Test-Retest Reliability:

Fifteen participants were re-interviewed within a one-week interval during the pilot phase to assess the stability of the instrument over time. The kappa statistic for categorical variables (e.g., presence of vaginal bleeding) ranged from 0.78 to 0.85, indicating substantial agreement.

3) Inter-Rater Reliability:

Since multiple medical officers completed the forms, consistency among raters was assessed. Two different raters independently evaluated ten randomly selected

patient records, yielding an inter-rater reliability coefficient (Cohen's kappa) of 0.80.

4) Pilot Testing:

A pilot study with 20 participants (not included in the final sample) was conducted to refine the instrument. Issues related to question interpretation and response options were identified and corrected.