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Enhanced Recovery after Cesarean Section (CS) versus Conventional Care in a Lower Middle-Income Country: A Randomized Controlled Trial

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Abstract

Background: Enhanced recovery after surgery (ERAS) has been tested in a wide variety of surgeries with promising outcomes. However, there is a need for a standardized, evidence-informed approach to both the development of new ERAS® Society guidelines, and the adaptation and revision of existing guidelines. Developing countries have limited resources and deserve every effort to improve economic status. **Aim of the Study:** to evaluate perinatal maternal outcomes of ERAS versus routine care protocols in women undergoing elective cesarean section (CS) in a lower middle-income country with limited resources ranked as a third most country performing CS worldwide using a multidisciplinary team (MDT) management. **Design:** A prospective randomized Controlled Trial. **Setting:** Outpatient department (OPD) and labor ward at the Woman's Health hospital, Assiut University, Egypt. **Participants:** Healthy pregnant women planned for elective CS (300 women) were randomly divided into a study group offered ERAS protocol and a control group offered regular care. **Results**: Repeat CS was the main indication of elective CS in both groups without significant difference (89 cases (59.3%) and 75 cases (50%) in both groups respectively). Other indications included cephalopelvic disproportion in 17 cases (11%) and 19 cases (12.6%), placenta previa in 28 (18.6%) and 34 (22.6%) cases, DM in 11 (7%) and 19 (12.6%) cases, and others in 5 (0.3%) and 3 (2%) cases in both groups respectively. The study group took much less time to eat and walk. It had significantly lower pain levels and postoperative problems, as well as much greater women's satisfaction and a shorter hospital stay (p = 0.001). **Conclusions:** Collaboration

of nursing, obstetricians and anesthesiologists is the cornerstone for a successful ERAS for CS. Significant better perinatal maternal outcomes encourage expansion of ERAS in lower middle-income countries with limited resources.

Keywords

Nursing, Cesarean Section, Enhanced Recovery

1. Introduction

Globally, Enhanced Recovery After Surgery (ERAS) protocols were introduced in clinical practice to reduce complication rates and hospital stay even for major surgeries [1]. If used for cesarean section (CS), it provides evidenced-based standardized care for the perioperative period, with benefits for maternal pain relief, mobilization, improved maternal-infant bonding, decreased opioid and rescue medication consumption, and shorter length of stay [2]. ERAS proved improvement of health care in high-income countries. However, there is a need for standardization of care, and for impacting outcomes, complications, and length of stay in low-middle income countries (LMICs) [3]. Egypt is classified by the World Bank as a lower middle-income country (LMIC) and the latest population council report [4] documented that Egypt ranked 3rd among world countries with an estimated rate of Cesarean section of 51.8%. Therefore, there is a great need to exert every effort to minimize costs particularly healthcare expenses to enhance community development process. This study aims to evaluate perinatal maternal outcomes of ERAS protocol in women undergoing elective cesarean section (CS) in a lower middle-income country with limited resources using a multidisciplinary team (MDT) management.

2. Subjects and Methods

This prospective study comprised women at the end of the third trimester planned for elective CS due to different indications and attending OPD of the Woman's Health University, Assiut University, Assiut, Egypt between June 2020 and December 2020. The study was approved by the ethical committee of the Faculty of Medicine (IRB approval #258691). Human material or human data were performed in accordance with the Declaration of Helsinki. Moreover, this randomized controlled trial (RCT) was registered in The ClinicalTrials.gov (NCT04360382). All cases gave a written consent to participate in this study. Sample size was calculated using G Power 3.1 [5]. A power calculation estimated that to detect an effect size of 36% difference in hospital stay, pain control, postpartum ambulation, and women's satisfaction between independent groups, with a p-value < 0.05 and 80% power, confidence level 0.95. Using computer-generated random tables, women were randomly assigned into group A (150 cases) offered enhanced recovery after surgery (ERAS) protocol while group B (150 cases) were left for the regular

hospital care in a single blinded randomization pattern. Inclusion criteria were pregnant women in the third trimester planned for elective CS with age range between 20 - 40 years. The study tool was evaluated by using the content of validity. A panel of three experts rated each scale's item for its relevance to the construct of health care to create the Item-level Content Validity Index (I-CVI). The ratings were given on a four-point scale, with one being "not relevant" and four being "very relevant". The (I-CVI) for each item was calculated using the percentage of experts who gave a rating of 3 or 4, expressing the importance of an item. The overall scale's content validity index (S-CVI) was determined by averaging the (I-CVI) replies from the five experts and dividing by the number of questions. In the case of (S-CVI), a score of .90 is regarded satisfactory. Moreover, a pilot study was carried out on the first 10% (30 women) of the total sample to test the content validity, feasibility, clarity, and objectivity of the tool as well as estimate, the time needed for data collection. Data were analyzed manually following pilot study. All cases were subjected to antepartum, intrapartum and postpartum care. Antenatally, every woman was assessed at a day before operation to gather all preoperative data including personal data, current or past medical or surgical history, obstetric history, and reports of routine investigations. Women allocated in control group B were thoroughly evaluated and prepared for CS according to her situation as practiced at our institution while study group A women were subjected to a preparatory phase of detailed explanation of the objective of ERAS and the required cooperation of the woman and response to the instructions given by the research team. Breast feeding education was offered to all cases of group A. Thereafter, an implementation phase started to collect data using a structured interviewing administrative questionnaire. The investigators explained all questionnaire items sufficiently and ticked in an observational checklist to check the performance of care introduced to women with stress on preoperative hydration and calorie consumption. In group B, women were advised to have nothing by mouth (NOP) at least 8 hours preoperatively while women in group A were instructed to stop solid food and clear oral fluid at least six to eight and two hours preoperatively respectively before operation. Patients in both groups were offered prophylactic antibiotics at the time of skin incision in addition to regular thromboprophylaxis measures. **Figure 1** shows flowchart of the study patients.

All CS were performed under spinal anesthesia without the use of morphia. Intraoperatively, group A were offered proper fluid balance, active warming (preheated intravenous fluids and cotton blankets), intra and postoperative gum chewing, delayed cord clamping, IONV, PONV (Intra and post-operative nausea and vomiting) prophylaxis and immediate skin to skin contact/breast feeding. Postoperatively, group A were allowed to have early oral intake and parenteral analgesics on a regular basis. Early mobilization and removal of Foley's catheter 2 hours after CS, early removal of dressing, meticulous monitoring vital signs, lactation consultation interview, continuous gum chewing, prevention of postoperative nausea and vomiting, community support (midwifes visit, physiotherapists, ect.)

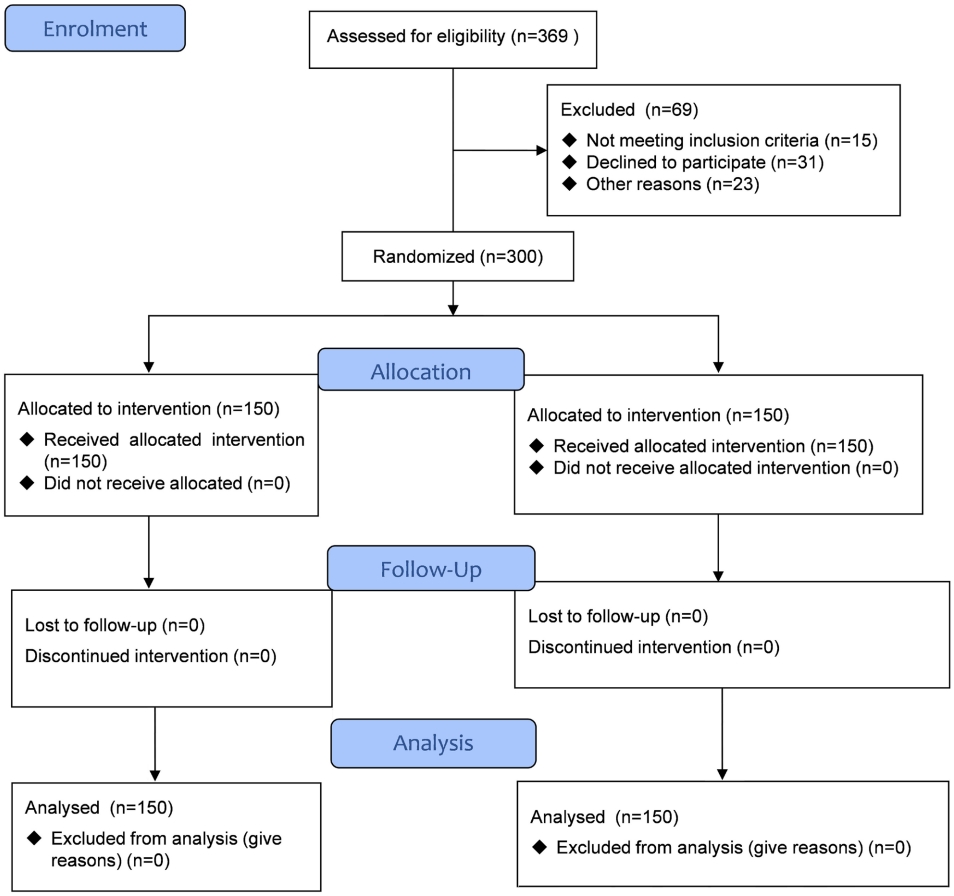

Figure 1. CONSORT 2010 flow diagram of the studied women.

and opportunity to go home on day one were also offered to them with complete instruction how to take care of the wound and to make home dressing after one week. On the other hand, women of group B were allowed to start oral feeding after hearing intestinal sounds in addition to lactation consultation interview, analgesics and vital signs monitoring. Follow up in group A was by telephone or any tool of communication (Wattsapp, messenger, …) after one week, two weeks and thereafter accordingly while women in group B were instructed to come back to the hospital after seven days for dressing and general check-up and thereafter accordingly. Primary outcome of this study included pain control, postpartum ambulation, and breast-feeding initiation while secondary outcomes were postoperative length of hospital stay and patient's satisfaction. The collected data were organized, categorized, coded, tabulated, and analyzed using the Statistical Package for social sciences (SPSS) version 18. Data were presented and tables and charts using numbers, percentages, means, standard deviation. Chi-square test of significance was used to find an association between variables. Statistical significance difference was considered at P-value ≤ 0.05 and highly statistical significance was considered at P-value ≤ 0.01. Ratability of the tool: for questionnaire 0.620, for satisfaction tool 0.986. There is no funding support of any part of this study.

3. Results

This study comprised 300 women planned for elective CS who were divided into two groups. Pilot study on 10% (30 women) of the total sample to test the content validity, feasibility, clarity, and objectivity of the tool were satisfactory. The commonest indication of elective CS was repeat CS seen in 89 cases (59.3%) and 75 cases (50%) in both groups respectively. Other indications included cephalopelvic disproportion in 17 cases (11%) and 19 cases (12.6%), placenta previa in 28 (18.6%) and 34 (22.6%) cases, DM in 11 (7%) and 19 (12.6%) cases, and others in 5 (0.3%) and 3 (2%) cases in both groups respectively. Group A were subjected to ERAS protocol while group B was left for regular hospital care. There was no statistically significant difference between both groups regarding socioeconomic data, obstetrics, medical and surgical histories, and basic investigations. Implication of ERAS protocol to group A resulted in significantly less pain immediately postoperative and at the time of discharge as shown in Figure 2. Likewise, shorter hospital stays, and rapid initiation of breast feeding were significantly better in the study group as shown in Figure 3. Postoperative complications were significantly less in group A as shown in Table 1. Generally, women in the study group were more satisfied than control group as shown in Table 2. Individual analysis revealed that age was the only sociodemographic item significantly related to patient satisfaction in both groups. Length of hospital stay was significantly shorter for urban residents in both groups. There were no significant predicators of postoperative complications in both groups as shown in Table 3. Occurrence of postoperative complications was an important contributing factor for patient satisfaction as shown in Table 4.

4. Discussion

Enhanced Recovery After Surgery for Perioperative Care society (ERAS® Society) was founded in 2010 to introduce and guideline implication of ERAS into many specialties and surgeries worldwide [6]. Despite promising and expanding

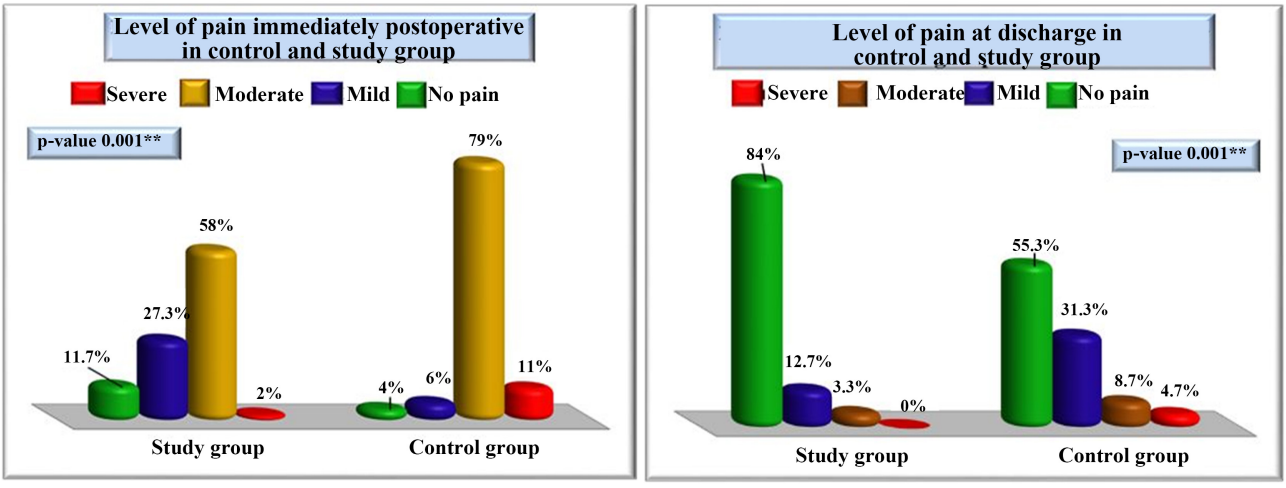

Figure 2. Level of pain immediate postoperative and at discharge in both groups.

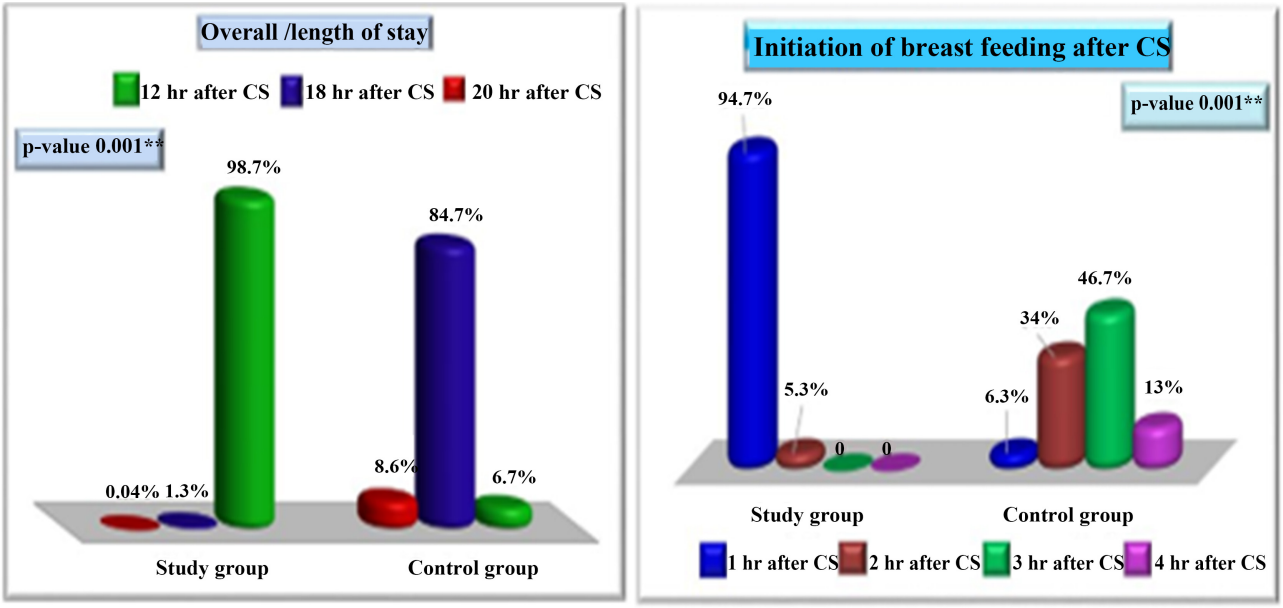

Figure 3. Length of hospital stay and initiation of breast feeding in both groups.

Table 1. Postoperative complications in both groups.

Postoperative complications	Study group		Control group		p-value
	No (150)	%	No (150)	%	
Non	150	100	144	96.0	0.002**
Wound infection	0	0.0	4	2.6	
Paralytic ileus	0	0.0	1	0.7	
DVT	0	0.0	1	0.7	

Table 2. Patient's Satisfaction in both groups.

Women's satisfaction	Study group		Control group		p-value
	No (150)	%	No (150)	%	
Dissatisfied	2	1.3	125	83.3	0.001**
Satisfied	125	83.3	25	16.7	
Very satisfied	23	15.3	0	0.0	

(**) highly statistical significant difference.

Table 3. Multiple regression analysis to assess the most significant predictors of personal characteristics, past medical, surgical history and obstetric history of postCS complications of study and control groups.

Item	Study group				Control group				Multiple regression	
	Occurrence of post CS complications				Occurrence of post CS complications					
	No		Yes		No		Yes			
	No (148)	%	No (2)	%	No (130)	%	No (20)	%	Sig	Exp(B)
Age: (years)										
<25 years	20	13.5	0	0.0	28	21.5	3	15.0		
25 - 35 years	82	55.4	2	100.0	69	53.1	9	45.0	0.233	0.067
<35 years	46	31.1	0	0.0	33	25.4	8	40.0		

Continued

Residence:										
Rural	60	40.5	2	100.0	50	38.5	9	45.0	0.280	−0.136
Urban	88	59.5	0	0.0	80	61.5	11	55.0		
Level of education:										
Illiterate	44	29.7	0	0.0	39	30.0	2	10.0		
Read and write	19	12.8	1	50.0	17	13.1	7	35.0		
Basic education	17	11.5	1	50.0	20	15.4	2	10.0	0.782	0.013
Secondary education	32	21.6	0	0.0	35	26.9	3	15.0		
University	36	24.3	0	0.0	19	14.6	6	30.0		
Work:										
Housewife	84	56.8	1	50.0	81	62.3	10	50.0	0.635	0.068
Employee	64	43.2	1	50.0	49	37.7	10	50.0		
Past medical history										
DM	136	91.9	2	100.0	113	86.9	17	85.0		
Hypertension	2	1.4	0	0.0	10	7.7	2	10.0		
Cardiac problems	3	2.0	0	0.0	2	1.5	0	0.0	0.806	−0.019
Renal problems	2	1.4	0	0.0	2	1.5	0	0.0		
Vascular problems	5	3.4	0	0.0	3	2.3	1	5.0		
Past surgical history:										
Cesarean section	90	60.8	1	50.0	92	70.8	17	85.0		
Abdominal surgery	55	37.2	1	50.0	36	27.7	3	15.0	0.130	−0.182
Vaginal surgery	3	2.0	0	0.0	2	1.5	0	0.0		
Gravidity: (wks)										
Primigravida	16	10.8	1	50.0	11	8.5	2	10.0	0.224	0.568
Multigraviga	132	89.2	1	50.0	119	91.5	18	90.0		
Parity:										
Primipara	17	11.5	1	50.0	16	12.3	3	15.0	0.159	−0.583
Multipara	131	88.5	1	50.0	114	87.7	17	85.0		
History of abortion:										
Yes	44	29.7	0	0.0	33	25.4	3	15.0	0.040	0.293
No	104	70.3	2	100.0	97	74.6	17	85.0		

Table 4. Comparison between women's satisfaction of study and control groups in relation to post CS complications.

Postoperative complications	Study group			Control group			p-value
	Dissatisfied	Satisfied	Very satisfied	Dissatisfied	Satisfied	Very satisfied	
	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)	
Non	2 (1.4)	123 (83.1)	23 (15.5)	113 (82.5)	24 (17.5)	0 (0.0)	0.028*
Wound infection	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)	0 (0.0)	0 (0.0)	
Pain	0 (0.0)	2 (100.0)	0 (0.0)	6 (85.7)	1 (14.3)	0 (0.0)	
Others	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	
Total	**2 (0.7)**	**125 (41.7)**	**23 (7.6)**	**125 (41.7)**	**25 (8.3)**	**0 (0.0)**	

practice of ERAS in different surgeries, there is a need for a standardized, evidence-informed approach to both the development of new ERAS® Society guide-

lines, and the adaptation and revision of existing guidelines [7]. Generally, ERAS protocols are interdisciplinary perioperative approaches that aim to reduce the body's stress reaction to surgery [8]. ERAS basically comprises limiting preoperative fasting, individualizing fluid management, offering nonopioid analgesics, utilizing minimally invasive surgery when feasible, and ensuring early postoperative urinary catheter removal, ambulation, feeding and discharge [9]. ERAS has been tested in many studies in CS and proved to be effective protocol. For instance, use of ERAS protocol in 3679 CS cases resulted in improved outcomes including decreases in opioid use, length of stay, and costs [10]. What's new in this study is implication of ERAS in a tertiary maternity hospital in Upper Egypt addressing two important issues. Firstly, tailoring of ERAS protocol to adapt a low-middle income country was proved to be successful in this study without adding more costs to the hospital expenses. Despite barriers [11] [12], ERAS during CS in developing countries should be focusing on basic elements first (eg, preoperative optimization, multimodal pain management, early postoperative mobilization) and making sure to prescribe effective low-cost available drugs [13]. In this study, with the cooperation with nursing staff, we succeeded to implement extensive preoperative assessment and constructed a detailed questionnaire in addition to proper patient health education that helped to improve patient acceptability of ERAS. Moreover, preoperative and intraoperative good hydration, warmth and gum chewing are simple and cheap effective factors. Intraoperative warmth has a favorable effect on both the mother and the neonate [14] [15]. Postoperative initiation of oral fluids within 2 hours resulted in a better postoperative course without any significant intestinal complications. Since a long time [16] [17], early feeding after CS was well tolerated and was associated with a more rapid return to a normal diet. It leads to accelerated return of bowel function, reduced hospital length of stay, without increased rates of complication or risk of postoperative nausea or vomiting. Moreover, it leads to reduced postoperative catabolism, improved insulin sensitivity and reduced surgical stress response [18]. Intraoperative and postoperative gum chewing promoted intestinal movement, reduced length of hospital stay and avoided postoperative ileus as shown in a previous study of our team [19]. An important contributing factor in the ERAS group is early removal of Foley's catheter after 2 hours postoperatively to allow early ambulation after resolution of the spinal anesthesia effect (usually within 3 hours from spinal injection of buvaicaine), shorter hospital stay and importantly reduced women's complaints of urinary symptoms as proved in a recent RCT [20]. A significant less postoperative and post-discharge pain with less need for analgesics in group A in this study may be attributed to all items of the ERAS protocol as previously stated [2]. According to the findings of the current study, women's satisfaction scores in the ERAS group were significantly higher than those in the control group which is a natural result to improvement of all aspects of the patient condition on ERAS. A recent prospective randomized trial on 240 CS women [21] concluded that ERAS reduced postoperative pain, incidence of intraoperative nausea, and average cost of hospitalization and also

improved patient satisfaction. In this study, as shown in **Table 1**, lower rate of postoperative complication in the study group may be attributed to early ambulation and shorter hospital stay. Moreover, ERAS was directly found to be associated with lower incidence of hospital-associated infections, postoperative ileus, and postoperative pulmonary complications [22].

The second important issue addressed by this study is the unfortunate report demonstrating that our country comes as a third most country performing CS all over the world despite being of limited resources [4]. Over-use of CS is posing a financial burden to women, their families, and the health system [4]. Of course, all measures should be seriously made to minimize this disproportionate rise of CS rate, and this is a collaborative responsibility of all health authorities including our tertiary Maternity Hospital. The current study comes in appropriate time to alleviate the aggressive effects of overused or used for inappropriate indications CS on the country economy. This study clearly and significantly informs that whenever strictly indicated CS, ERAS protocol would help save money and minimize burden on the already exhausted health facilities. Limitations of this study included small sample size which may attributed to the obligation of the couple to pay considerable basic fees and to donate at least half liter of blood by the woman's relatives as a prerequisite for hospital admission. Another limitation is the missing of correlation of results with the number of previous CS and other indications of elective CS. From this study, it is concluded that collaboration of nursing, obstetricians and anesthesiologists is the cornerstone for a successful ERAS for CS. Significant better perinatal maternal outcomes encourage expansion of ERAS in lower middle-income countries with limited resources.

5. Ethical Issues

There was no risk for study subjects during application of the research. The study followed common ethical principles in clinical research. Women were assumed that all information obtained would be confidential and would be used only for the purpose of study and they had the right to refuse to participate and or withdraw from the study without any rational at any time. Written consent was obtained from women or guidance who participated in the study, after explaining the nature and purpose of the study.

Author Contributions Section

AD (corresponding author) conceptionized this paper, wrote, and revised the paper. BAH collected data and made statistical analysis (with the aid of a statistician), wrote the thesis and defended it. MFM and EMY supervised BAH and made step by step follow-up of the work, reviewed the work and attended thesis defense. AD reviewed the final form of the paper and made some corrections.

Conflicts of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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