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ORIGINAL ARTICLE

Childbirth Checklist and Complications at Zagazig University Hospitals

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ABSTRACT

Background: The surgical environment needs special challenges to safeguarding patient safety. The checklist of WHO was presented as one means of reducing harm and improving the safety of patient during operating theatre. 147 Pregnant women underwent to obstetric operation during time of study and hospitalized for more than 24 h after the operation and Obstetric surgical teams performance.

Methods: Cross sectional study conducted at operating room of obstetric department in Zagazig University Hospitals during the period of time from May 2017 to February 2018 for observation of Checklist of Surgical Safety for all included patients in this study by medical team.

Results: Items of SSC sign in were fulfilled with percentage above 90% except that patients had confirmed and prophylaxis of venous thrombo-embolism was needed only in 3.4% of studied cases. Items of SSC time out were fulfilled with 100% as sterilization was been confirmed, Resuscitation unit was on , Resuscitation equipment was present and working . Other items were less as vocally confirmation of procedure, prophylatic antibiotic been administrated through the final 60 minutes before incision , expected losing of blood and any patient-specific concerns (80.3%, 85.7%, 87.1% and 95.9%) .Items of SSC sign out were fulfilled 100% .

Adverse events were 31.1% represented in 23.1% intraoperative hemorrhage and 5.4% bladder injury. There was no infectious adverse events in our study. 31.3% of our studied cases entered ICU post operation .

Conclusion: Implementation of SSC was associated with reduction in complications and mortality in obstetric operations.

Keywords: childbirth checklist, Surgical safety, obstetric complications

INTRODUCTION

Dropping maternal mortality is a chief concern all over the world. It was predictable about 830 deaths occurred daily in the maternal side in 2015; especially 95% of this deaths occurred mostly in poor and low-income countries and above 60% of deaths takeplace in Africa[1].

Indeed, some countries partially had attained MDG 4 – reduction of child mortality, and MDG 5 – enhance the health of maternity [2]. Usage of evidenced-based essential birth practices (EBPs) for prenatal be concerned routinely and of complications management for the duration of childbirth is solution to realizing best care quality and decreasing child and maternal rate of deaths[3]. After successful checklist of surgical safety in diminish surgical obstacles [4], introduction of the Safe Childbirth Checklist (SCC) was developed in 2009 by WHO .

SCC involved 29 necessary practices for birth objecting most maternal deaths reason, intra-partum-associated neonatal deaths and stillbirths which occur in services worldwide[5].This tools of low-cost which is applied to be available for attendants of birth to confirm that well-timed, practices of lifesaving are carried out for each tool-based birth. The SCC is focal pointed on care delivered for births at term gestation as these represent the overwhelming majority of births and designed to address the care quality at 4 critical periods in the continuum of birth including: facility of admission, the moment of pushing (or prior to cesarean section), once following the birth (within 60 min.), and discharge period[6]. Aim of the work was To improve the health and well-being of pregnant women undergoing obstetric surgery at Zagazig university hospitals by observation of medical team performance inside operating rooms ,adverse events and surgical safety checklist application in 147 pregnant women underwent to obstetric operations

METHODS

A cross sectional study was conducted at the operating room of obstetric department of Zagazig University Hospital during the period from May 2017 to February 2018 on 147pregnant women entered operating room of obstetric department at Zagazig university hospitals for delivery or termination of pregnancy during time of study and hospitalized for more than 24 h after the operation also surgical teams performance towards checklist for surgical safety were included during the period of the study. Written informed consent was obtained from all participants and the study was approved by the research ethical committee of faculty of medicine , Zagazig university . The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. For each women, complete history and clinical examination was obtained including personal, present , past history (medical and surgical)and complete obstetric data was collected (gravidity , parity ,Gestational age , previous abortion ,normal vaginal delivery and cesarean section) also operation type and date as well as anesthesia types were recorded.

Surgical Safety Checklist for obstetrics operations observed for all included patients in this study by medical team in 3 phases

1-*Sign in* (before anesthesia is administered)

Confirms the identification , procedure, and consent of patients. The controllers examins with the anesthetist the risk of losing blood, difficulty in airway, any allergies,and preoperative prophylatic venous thrombo-embolism if necessary. The presence of surgeon is highly advocated due to surgeon is able to expect losing of blood and possible complications.

2-Time out (immediately before skin incision):

During this period, each member of the team introduces him or herself by name and role. The identification of the correct patient and procedure by reading the consent form audibly and opportunity is likely to verify antibiotics before operation. Finally, the team of surgical, anaesthesia, surgeons and nurses can introduce any apprehensions before surgery commencement.

3-Sign out(before the patient is taken out of the operating room):

The team reviewed the following:

The performed operation,Completion of sponge and instrument counts, surgical samples or any equipment malfunction or that requires to be labelled and any issue concerning management postoperatively. Each patient was followed up in obstetric department yard for 24 hours after operation to record incidence rate of death and/or complications .

STATISTICAL ANALYSIS

Data analysis was take placed using the software SPSS (Statistical Package for the Social Sciences) version 20. Quantitative and Categorical variables were illustrated using their means standard deviations and their absolute frequencies ,respectively. Kolmogorov-Smirnov (distribution-type) and Levene (homogeneity of variances) tests were applied to confirm hypo thesiss for the usage of parametric tests.

To compare means, independent sample t test was applied when appropriate. Nonparametric test (Mann Whitney) was used to compare means when data was not distributed normally and to compare medians in categorical data. Categorical data were compared using Chi-square test or Fischer's exact test when appropriate.

The level statistical significance was set at 5% ($P<0.05$).

Highly significant difference was present if $p\leq0.001$.

RESULTS

Demographic data of 147 studied Patients was showed in table (1) as age was range from 17 to 42 years old .The largest percentage of our studied cases was multi gravidity and parity .91.9 % of age of gestationstudied cases was after 28 weeks and The gestational age mean was 34.71 range from 8 to 42 weeks . Table (2) showed adverse events in this study were 31.1% represented in 23.1% intraoperative hemorrhage and 5.4% bladder injury . There was no infectious adverse events in our study. 31.3% of our studied cases entered ICU post operation . Operative data of studied cases was showed in table (3) as 72.8 % of our studied cases underwent to urgent operation and 75.5% of our operations were lower uterine segment cesarean section although cesarean hysterectomy was represent 12.2% There was statistically highly significant difference between cesarean hysterectomy and occurrence of intraoperative complications . Table (4) showed the completion of "sign in" items of the surgical safety checklist in relation to occurrence of complications in which there were statistical significant differences between the two groups (complicated and non-complicated) as regard completion of anesthesia safety check, pulse oximeter functioning, estimation of presence of allergy and, estimation of risk of blood loss >500 ml which were significantly higher among uncomplicated group **($p<0.05$)**.

Items of checklist for surgical safety time out were showed in table (5) There is statistically significant difference among complicated and uncomplicated groups regarding completion of time out surgical safety checklist except for nursing team review equipment issues. All these items were highly significant higher in uncomplicated groups

(p<0.05). Table (6) showed items of surgical safety checklist sign out were fulfilled 100% as the instrument, sponge and needle counts were correct . other items were poor applications as recording procedure name, addressing equipment problems and providing review key. There were statistical significant changes between the two groups (complicated and non-complicated) as regard completion of *Sign in* anesthesia safety check, pulse oximeter functioning, estimation of presence of allergy, Essential radiological imaging displayedand, blood availability for risk of blood loss >500 ml *Time out* surgical safety checklist except for nursing team review equipment issues. *Sign out* as regard recording procedure name, specimen label and review key

All these items were highly significant higher in uncomplicated groups (p<0.05)

Table (1): Demographic data of the studied Patients

Variables		Data			
		N(%)	Mean ±SD	Median	Range
age (years)			29.47±5.71	30	17-42
Distribution of Gravidity	1-3 4-6 7-10	72 (49%) 65 (44.2%) 10 (6.8%)		3	1-10
Distribution of parity	0 1-3 4-6	28 (19%) 97 (66%) 22 (15%)		2	0-6
Gestational age (weeks)	<28 28-38 38-42	12 (8.2%) 77 (52.4%) 58 (39.5%)	34.71±8.05	37	8-42

Table (2) : Complications in studied cases

Adverse Events	N	%
Intra operative hemorrhage	34	23.1
Organ injury during a procedure (Bladder injury)	8	5.4
Post-operative ICU admission	46	31.3
Unplanned return to the OR	1	o.7
Intra-operative death	0	0
SSI during hospitalization	0	0

ICU : Intensive Care Unit OR: Operating Room

Table (3): Relation between type of operations and occurrence of complications

	Uncomplicated		**Complicated**		**Test**	**p**
	N (101)	**%** (68.7)	**N (46)**	**%** (31.1)		
Type of operation:						
Urgent	69	68.3	38	82.6	3.259	0.071
Not urgent	32	31.7	8	17.4		
Type of operation:						
Left salpingectomy	2	2	2	4.3	0.669	0.413
CS hysterectomy	6	5.9	12	26.1	11.938	<0.001**
D&C	8	7.9	0	0	3.053	0.049*
Vaginal delivery	2	2	0	0	0.923	0.337
Repair of rupture uterus	2	2	2	4.3	0.669	0.413
CS	81	80.2	30	65.2	3.863	0.051

CS : Cesarean Section D&C : Dilatation and Curettage

Table (4): Items of checklist about "sign in" completion in relation to occurrence of complications

"Sign in" items	uncomplicated (N.=101)		complicated (N.=46)		X2	p value
Patient has confirmed:	**N.**	**%**	**N.**	**%**		
-Identity						
- Site	100	99	46	100.00	Fisher	1
- Procedure	42	41.6	17	37	0.282	0.596
- Consent	97	96	43	93.5	Fisher	0.678
	101	100	44	96.7	Fisher	0.09
Site marked	101	100	46	100		
Anesthesia safety check completed	96	95	37	80.4	7.834	0.005*
Pulse oximeter on patient and functioning	95	94.1	40	87	6.068	0.014*
Patient has a known allergy?	101	100	40	87	Fisher	<0.001**
Difficult airway/ aspiration risk?	88	87.1	45	97.8	Fisher	0.065
Essential radiological imaging displayed?	99	98	41	100	Fisher	0.013*
Blood availability for risk of > 500ml blood loss?	98	97	37	80.4	Fisher	0.002*
venous thromboembolism prophylaxis	4	2.7	1	0.68	Fisher	1

*p<0.05 is statistically significant

**p≤0.001 is statistically highly significant

Table (5): Items of checklist about "time out" completion in relation to occurrence of complications

"Time out" items	Uncomplicated (N.=101)		complicated (N.=46)		X2	p value
Confirm all team members have introduced themselves by name and role	**N.** **43**	**%** **42.6**	**N.** **8**	**%** **17.4**	**8.846**	**0.003***
Surgeon, anesthesia professional and nurse verbally confirm:						
- Patient	56	55.4	20	43.5	24.068	<0.001**
- Site	46	45.5	6	13	14.604	<0.001**
- Procedure	88	87.1	30	65.2	9.582	0.002*
Antibiotic prophylaxis been given within the last 60 minutes before incision	95	94.1	31	56.69	18.357	<0.001**
Resuscitation unit on , Resuscitation equipment present and working	101	100	46	100	0	1
<u>Anticipated critical events</u>						
Surgeon reviews:						
- The critical or unexpected steps.						
- Operative duration.						
- Anticipated blood loss.	30	29.7	2	4.3	Fisher	<0.001**
Anesthesia team reviews:	20	19.8	0	0	Fisher	0.001**
- Are there any patient-specific concerns?	96	95	32	69.6	18.238	<0.001**
Nursing team reviews:						
- Has sterilization been confirmed?	101	100	40	87	Fisher	<0.001**
- Are there equipment issues or any concerns?7	101	100	47	100		
	7	6.9	0	0	Fisher	0.099

*p<0.05 is statistically significant

**p≤0.001 is statistically highly significant

Table (6): Items of checklist about "sign out" completion in relation to occurrence of complications

"Sign out" items	Uncomplicated (N.=101)		complicated (N.=46)		X2	p value
	N.	%	N.	%		
The name of the procedure recorded	42	41.6	10	21.7	5.445	0.02*
The instrument, sponge and needle counts are correct.	101	100	46	100.00		
The specimen is labeled	75	74.3	21	45.7	11.441	<0.001**
There are any equipment problems to be addressed	2	1.98	0	0	Fisher	**1**
Surgeon, anesthesia professional and nurse review the key concerns for recovery and management of this patient	14	13.9	1	2.2	2.46	**0.038***

*p<0.05 is statistically significant **p≤0.001 is statistically highly significant

DISCUSSION

Patient safety is a priority in modern health care systems. From 3% to 17% of hospital admissions result in an adverse event**,[21]**and almost 50% of these events are considered to be preventable An adverse event is an unintended injury or complication caused by delivery of clinical care rather than by the patient's condition. **.[22]** This study included 147 pregnant women underwent to obstetric operations at Zagazig university hospitals . Among them 111 women underwent to CS , 18 women underwent to CS hysterectomy ,8 women underwent to D&C ,4 women underwent to left salpingectomy , 4women underwent to repair of rupture uterus and 2 women underwent to vaginal delivery and hospitalized more than 24 hours.

Operative data of studied patients include72.8 % urgent operation .The SSC consists of three sections, the sign-in phase, the time-out phase and the sign-out phase. Before induction of an aesthesia (sign in) during this phase the identity of the woman, the procedure and consent was confirmed. (99% &95.2%&98.6% respectively)The anesthetist and pediatrician confirm that the an aesthetic and neonatal safety checks are complete with no problems.A pulse oximeter is confirmed to be on the patient and in working order (91.8%). The surgeon and anesthetist then confirm that the patient has no allergies (95.9%) and does not have a difficult airway (90.5), and that there is no risk of aspiration or excessive blood loss(91.8%).

Items of checklist for surgical safety sign in were fulfilled except that patients had confirmed site and marked it(40.1%). detecting the procedure site is serious to overcome wrong-location surgery. Specially, site marking could be achieved with the participation of patient. These results were similar to that of Todd et al prospective observational audit study for SSC implementation where 94% of sign in was done [8]. Giles et al observational study of SSC using in Australian operating theatres .The checklist items is ordinarily observed to be attended to the staff of operating theatre as distinguished during comments were: correct patients who represented (99%) and procedure which represented (97%), the patient with allergies represented (80%) but the signed consent form by patient represented (36%) which is less than our study[9]. and Bliss et al study found that most individual components checklist were completed by >90% [10]. There were statistical significant changes between occurrence of intraoperative complications and sign in SSC as regard completion of anesthesia safety check, pulse oximeter functioning, estimation of presence of allergy and, estimation of risk of losing blood >500 ml which were significantly higher among uncomplicated group (p<0.05). These results were similar to that of Haridarshan et al as there was a significant reduction in complications of anesthesia, both within and following surgery post-implementation (2.78 to 1.61%, 1.4 to 0.8%,respectively) forms of intra-operatively and postoperatively. As well as in reduction of intraoperative surgical complications from 5.1 to 2.41%[11] .

Before the skin incision (time out) and after induction of the an aesthetic during this phase all members would have introduced themselves (24.5%) in contrast to Russ et al study were team members were absent in more than 40% of cases, and they failed to pause or focus on the checks in more than 70% of cases [12]. In our study the identity and procedure for patient are once more confirmed (51.7% &80.1%). The surgeon appraisals whether extra procedures are sketched and there were concerns for the site of placenta. Moreover, the anesthetist reported any apprehensions about the patient, and the nursing team corroborates the instruments sterility (100 %) and that there are no issues regard equipments (4.8%). The team confirms that prophylactic

antibiotic/s, have been administered to the patient(85.7%) in agree with90% of SSC time Out completed in Todd et al study who suggested that there was statistically significant changes among complicated and uncomplicated groups regarding completion of time out surgical safety checklist except for nursing team review equipment issues [8]. All these items were highly significant higher in uncomplicated groups ($p<0.05$).

Before the patient leaves the operating room (sign out) at the end of the operation during this phase the nurse confirmed that the procedure has been recorded(35.4%) and that the instrument, swab and needle count is correct(100%). in contrast to 56% in Giles et al., study. Specimens are confirmed to be appropriately labeled(65.3%) similar to Russ et al., study sign-out was not completed in 39% of cases, largely due to uncertainty about when to conduct it, and only 57% conducted a Sign Out in Todd et al.

Blood loss is confirmed to have been recorded. If there were any equipment concerns(1.4%), these problems have to be addressed before the next procedure. The baby/babies are correctly identified. The surgeon, anesthetist and recovery room nurse review the key concerns for recovery and decide whether the patient needs further management(10.2%). There was statistical significant changes between the complicated and un complicated groups as regard recording procedure name, specimen label and review key in which the they were higher in uncomplicated group ($p<0.05$)Complications is the main cause of deaths in these women during and following pregnancy and/or childbirth. The majority of these obstacles noticed during the gestational periods and almost are avoidable by treatments. Other difficulties may exist prior to pregnancy but are worsened during gestation when not managed as partition of the care for pregnant women[13].In our study there was no women death intraoperative or postoperative during hospitalization. These results were similar to that of Haugen and Rodrigo studies no died women on the intervention day in any studied periods [14][15]. Our results was in agreement with Other studies showed reduction of mortality rate after implantation of SSC as Kabongo et al study found reductions in perinatal mortality rates from 22 deaths/1000 deliveries to 13.8/1000 deliveries largely due to a drop in fresh stillbirths [16].Intraoperative death reduced from 1.4to 0.4% and deaths follow operation reduced from 12.04 to 8% in Haridarshan et al study , also in Rodrigo et al who reported a retrospective pre- and post- surgical intervention of two cohorts study for patients who admitted (n = 1602) in a tertiary teaching hospital death rate at one month and reduced from 1.5% to 0.9% (P = 0.35) and there was a mortality reduction after one month from 1.5% at period of baseline to 0.9% period after implementation in the checklist (P = 0.356) .

In this study there was 31.3% of our studied cases had adverse events .This results was similar to Rodrigo et al total AEs minimized from 60.4 to 37.0 for non-elective patients after SSC implementation ,less than prospective study of Mehta et al study which was to assess the effect of checklist for Surgical Patient Safety System (SURPASS)on the patient's outcome following surgery[17]. Prior to checklist for implementation, a notable obstacles were recorded in 66.66% and 77.23% of elective and emergency cases, respectively . while follow checklist for implementation, a notable obstacles were recorded in be 51.09% and 67.50% in elective and emergency cases ,respectively , and more than a retrospective cohort study of Aibar et al including 816 women presented in the obstetrics departments at 41 hospitals that took part in the National Adverse Effects Study in Spain (ENEAS) and an conservatory of this study in all hospitals situated in two Autonomous Regions were the cumulative incidence with obstetric care-related AE in patients was 3.6 %[18].The adverse events in our study represented in non-infectious AEs as intra operative hemorrhage 23.1%, Organ injury during a procedure 5.4% ,Post-operative ICU admission 31.3% and Unplanned return to the operating room 0.7%.There was no infectious AES in our study in contrast to Rodrigo et al study rate of infectious AEs decreased from 13.9% to 9.6% and Shankar study as complications more than half (60.3%) were surgical wound infections[19].

Finally our results were in agreement with Rodrigo et al study Following implementation of the checklist, the rate of AEs per 100 patients reduced from 31.5% to 26.5% and Tuyishime et al quality improvement project took place in the Masaka District Hospital in Rwanda. Observations of the 29 EBPs were done before and after WHO SCC implementation .The overall EBP compliance rate raised from 46% pre-intervention to 56% post-intervention (P =0.005). Significant improvements were seen in 11 out of 29 EBPs[20].

CONCLUSION

This study revealed that implementation of checklist for surgical safety conducted by WHO was connected to reduction in major intra operative and post-operative complications, mortality in obstetric department at Zagazig University Hospital. It was found that there were statistical significant improvement in the overall complications specifically SSI, retained foreign body , bleeding need more than 4 units of blood, unplanned return to OR and death rate in cases with

high percentage of surgical safety checklist application.

Conflict Of Interest: No

Financial Disclosures: No

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