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Original Article

A Multicentric Study of Practice of Surgical Site Marking

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Abstract

Objective: The objective of this study was to evaluate the process of surgical site marking (SSM) and compare the actual practice with the recommended practices. **Methodology:** This was a prospective study involving 768 patients from 19 accredited hospitals located in different regions of India and are members of the Consortium of Accredited Healthcare Organizations. The study was performed over a period of 45 days. While performing the study, proportionate to size sampling methodology was used. The total number of surgeries performed per month in the top six specialties (in terms of volume) of the participating hospitals were considered. Further, in a particular specialty out of the six top specialties of the hospital, the auditors randomly selected the top three most frequently performed surgeries and studied the SSM process as per the predefined Pro forma. The observations of the study were then compared (and analyzed) with the recommended practices as per the guide to SSM, High 5 S by Haute Autorité d e Santé and CEPPRAL, October 2012. **Results:** In this study, the actual side marking was done in 85% of the surgeries that required side marking and 81% had site marking done. Surgical site in majority of the patients was marked in preoperative bay (43.8%). Moreover, surgical sites in 57.9% of the patients were marked by operating surgeons themselves, while others were delegated to nurses or technicians. Surgical side marking was done on 88.3% of the surgeries performed on paired organs. In surgeries with laterality such as hernia repair, the marking was done in 90% when the open surgery was performed and 70% for laparoscopic surgeries. Surgical site markings were visible before and after the site preparation in 63.2% and 46.5% of patients, respectively. It was pertinent to note that the SSM markings were not visible in 17.8% and 34.5% of the cases before and after skin preparation and 19% did not have the site marking. This percentage is quite high and thus an important area of concern. In addition, only in 36.1% of the patients, the SSM was visible within 6 inches from the incision. Crosses (27.7%) were the most common markings used. It is crucial that the nurses checked the patient's SSM only in 42.7% of cases in the wards and 74.1% of cases preoperatively in operation theater (OT), thereby a strong need to strengthening, streamlining, and standardization of the process of SSM to avoid missing out of cases. The surgical site marks were verbally and physically checked in 6.8% and 67.3% of the patients and not checked for 25.9% of the cases. Similarly, the surgical team inside the OT checked the surgical site marks verbally and physically in 17.6% and 77.7% of the patients, respectively. **Conclusions:** The findings of this study demonstrate that SSM procedure is practiced in majority of the hospital audited, but operating surgeons involved in this procedure were far from desired. Surgeons should be sensitized and educated and specialty-based protocols are to be framed so that they are strictly followed. There is a need to bring about national guidelines on the safe practice of SSM. Once protocols are in place and implemented, further studies will be required in future to assess their practice.

Keywords: Hospital errors, markings, patient safety, preventable medical errors, quality in hospitals, quality in surgical services, sentinel event, surgery markings, surgery, surgical site marking, wrong side surgery, wrong site surgery

Introduction

Surgeries form essential and indispensable part of the health-care delivery system for managing various health conditions. As per an estimate by Weiser *et al*., globally 312.9 million surgeries were performed in 2012, of which nearly one-third were cesarean sections.[1] However, with the rise in the number of surgeries performed, number of cases with wrong site surgeries (WSSs), one of the serious reportable sentinel events, have also increased.[2] In addition, it is said that WSS is as old as surgery itself.

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From the definition point of view, WSS is a surgery undertaken on the wrong person, the wrong organ or limb, wrong side, or the wrong vertebral level, and can include invasive procedures such as dermatological, obstetric and dental procedures, regional blocks, and emergency surgical procedures performed in the operation theater (OT).[3] It is estimated that WSS occurs at a rate of 1/112,994 surgeries.[4] In addition, complications arising as a result of wrong-site, wrong-procedure, and wrong-patient selection may be as high as 1/27,322 surgeries.[5]

The recent sentinel event statistics released by The Joint Commission (TJC) report WSS as the third most common event (12%).[6] Among various causes of WSS, failure to use surgical site marking (SSM) is one of the most common causes.[3] de Vries *et al*. reported that wrong person, site, or side events are the 3rd most common reasons (16%) for medical insurance claim, in 12% cases, the principal reason was the incorrect use of or lack of a marking procedure. Around 75% of these events could have been averted using suitable SSM procedure.[7] In addition, it can be stated that a lack of preventive strategies during the preoperative period is the most common cause of WSS.[8]

The SSM forms an important part of "Check-in," "Sign-in," and "Time-out" elements of the WHO's Surgical Safety Checklist.[9,10] The findings of a Canadian study suggests that only 48% of hand surgeons follow the preoperative SSM procedure; however, those who had made mistakes in the past were the most compliant.[11] In addition, as per the findings of TJC targeted solutions tool for Safe Surgery Program, the nursing staff helped in decreasing the chances of WSS from 16% to 9%, 86% to 53%, and 73% to 25% in surgical booking, preoperative/holding, and OT, respectively.[10]

However, studies assessing the practice of preoperative SSM in Indian patients are lacking. Thus, this study was planned with the objective of evaluating the methods of SSM and compare the actual practice with the recommended practices.

Methodology

This was a prospective audit-based study involving 19 accredited hospitals which are members of Consortium of Accredited Healthcare Organisations from different parts of India. The study was approved by the institutional ethics committee of the respective hospitals and performed over a period of 45 days in the months of September and October 2018. Proper attention was given so that none of the identifiable patient parameters or patient personal data were captured during this study. A predesigned pro forma was used by the auditors to capture the relevant information. Regarding the methodology employed in the study, the auditors of the participating hospitals were trained through a webinar on the process of capturing of data in the predefined Pro forma, inclusions and exclusions to ensure clarity and data accuracy.

Sampling method and sample size

The total number of surgeries per month of the top six specialties (in terms of volume) of the participating hospitals were considered (termed as total population). A total number of surgeries performed in the month of July 2018 were used as a basis for deciding the top six specialties of the hospital, in terms of the volume. A 15% of the total population was considered to be eligible for the study.

The proportionate to size sampling methodology was used to further define sample size for the various specialties offered by the hospital. This means that greater sample was drawn from specialties with higher volumes, while smaller sample was drawn from specialties with smaller volumes. This varied from hospital to hospital, which were participating in the study.

The hospital auditors randomly selected and studied the SSM in the top three most commonly performed surgeries, in that particular specialty. The surgeries chosen were not limited to those that required site and side marking. Seven hundred and sixty-eight patients across 19 hospitals were included in the study.

Statistical analysis

Data were collected and collated in Microsoft Office Excel 2016 and further analyzed. Data are represented as frequencies and percentages. The observations of the study were then compared (and analyzed) with the recommended practices as per the international guidelines – The Guide to SSM, High 5 S by Haute Autorite d e Sante and Cepral, October 2012.

Results

In this study, the actual side marking was done in 85% of the surgeries that required side marking and 81% had site marking done [Table 1]. Majority of the patients underwent elective surgical procedures (i.e., 96.9%) and had identification band (i.e., 95.2%) present at the time of operative procedure, surgical sites were marked in preoperative bay (43.8%), followed by wards (39.6%). In addition, majority of the patients had their surgical sites marked by doctors (57.9%), followed by nurses (25.1%) [Table 2].

Povidone-iodine (63.9%) followed by betadine (14.9%) were the most common agents used to prepare the surgical sites. In majority of the patients, SSMs were visible both before (63.2%) and after (46.5%) the site preparation. However, it is important to note that visibility of SSM was not there in 17.8% and 34.5% of the cases before and after skin preparation, respectively. This is quite a high percentage of cases and can lead to significant preventable medical errors and is definitely an area of concern. In addition, in 36.1% of the patients, the SSM was visible within 6 inches from the incision [Table 3].

Crosses (27.7%) followed by arrows (25.4%) were the most common markings used. In addition, among the other techniques of marking, stickers (5.7%) were most commonly used [Table 4].

Preoperatively, nurses checked the surgical site marks (74.1%) of the patients after they were shifted to the OT, whereas nurses

Table 1: Distribution of the patients on the basis of side and site marking

	Total audited (*n*)	Marking not applicable (*n*)	Marking applicable (*n*)	Marking done, *n* (%)	Marking not done, *n* (%)
Side marking	768	195	573	487 (85)	86 (15)
Site marking	768	269	499	404 (81)	95 (19)

Table 2: Distribution of the patients on the basis of type of case, and where and by whom they were marked

Characteristics	*n* (%)
Type of case (*n* = 768)	
Elective	744 (96.9)
Emergency	24 (3.1)
Identification band (*n* = 768)	
Present	731 (95.2)
Absent	37 (4.8)
Marked at (*n* = 573)	
Preoperative bay	251 (43.8)
Wards	227 (39.6)
Intra-operative	9 (1.6)
Not marked	86 (15)
Marked by (*n* = 573)	
Doctors	332 (57.9)
Nurses	144 (25.1)
Operation theater technician	11 (2)
Not marked	86 (15)

Table 3: Distribution of the patients on the basis of visibility of surgical site marking

Characteristics	*n* (%)
Visibility of SSM before skin preparation (*n* = 499)	
Yes	315 (63.2)
No	89 (17.8)
Site marking not done	95 (19)
Visibility of SSM after skin preparation (*n* = 499)	
Yes	232 (46.5)
No	172 (34.5)
Site marking not done	95 (19)
Visibility of SSM with 6 inches from incision (*n* = 499)	
Yes	180 (36.1)
No	224 (44.9)
Site marking not done	95 (19)
Table preparation (*n* = 768)	
Povidone iodine	491 (63.9)
Betadine	114 (14.9)
Chlorhexidine	68 (8.9)
Chlorhexidine and povidone iodine	65 (8.4)
Normal saline	30 (3.9)

SSM: Surgical site marking

checked only 42.7% of the patients, while they were still in the wards, thereby highlighting another area of improvement where we need to strengthen our SSM process by standardization and ensuring double checks to avoid missing out of cases. Checking was done physically in 67.3% of the cases preoperatively and verbally for 6.8%. It was not checked preoperatively for 25.9%. Similarly, preoperatively, the surgical site marks were checked by the surgical team in OT, physically in 77.7% of the cases, verbally in 17.6%, and not done in 4.7% [Table 5].

Discussion

Preoperative SSM is usually encouraged as it has a considerable value in stimulating correct site surgeries, including operating on the correct side of the patient and/or the correct anatomical location or level.[12] The SSM is part of the series of checks and is helpful in preventing WSS in agreement with the WHO checklist before incision.[9]

International Guidelines on SSM – The Guide to SSM High 5 S by Haute Autorite d e Sante and Cepral, October 2012, provides the necessary guidance to define inclusions and exclusions for the process of SSM. The SSM should be performed after all information regarding the patient's identity, the procedure to be performed, and the surgical site to be operated has been checked and cross-referenced.[8] In cases of life-threatening emergencies, if the time needed for performing SSM results in an extra risk to the patient then such SSM procedures are exempted. Other conditions where SSM is exempted are the procedures involving teeth or mucous membranes, bilateral surgery or circumstances where laterality cannot be confirmed Before examination under anesthesia.[8,13] While SSM is to be performed on all patients that are supposed to undergo incision or percutaneous intervention involving multiple surfaces or structures (i.e., flexor or extensor, lesions, fingers, and toes), laterality (i.e., a single limb or one of a pair of organs), or levels (i.e., spine and vertebra).[8]

Timing of SSM is of prime importance and is to be performed before the patient is shifted to OT, and ideally before induction of anesthesia in an awake and conscious patient. While ambiguity in the markings is to be avoided. The type of mark to be used is decided by each health-care setup based on an organized and harmonized marking procedure; however, arrows are preferred.[8,13]

Ideally, SSM should be performed by the operating surgeon. However, this can be delegated to a doctor or nurse, only if they are involved in the surgery or directly concerned with the patient preparation process.[8,13] The checklist coordinator is chief person accountable for confirming that surgical site of each patient has been correctly marked before they are shifted to OT. The operating team is accountable for performing the final "time out" and for confirming that the correct surgical site has been marked before the incision.[8]

In this study, 57.7% and 25.1% of surgical sites were marked by doctors and nurses, respectively. However, Bathla *et al*.

Table 4: Distribution of the patients on the basis of marking signs and techniques used

Characteristics	*n* (%)
Marking signs used (*n* = 573)	
Cross mark	159 (27.7)
Arrow mark	146 (25.4)
Dressing at site	18 (3.2)
Writings	17 (2.9)
Drawings	10 (1.7)
Circles	49 (8.5)
Straight lines	13 (2.5)
Square	6 (1.1)
Sticker	33 (5.7)
Micropore	23 (4.1)
Band	13 (2.2)
Not marked	86 (15)

Table 5: Distribution of the patients on the basis of checking of surgical site marking at different places

	n	
	Ward (%)	Preoperative in OT (%)
By nurses (*n* = 768)		
Yes	42.7	74.1
No	57.3	25.9
	Physical (%)	Verbal (%)	Not done
Preoperative by nurses (*n* = 569)	67.3	6.8	25.9
Intra-operative by team	77.7	17.6	4.7

OT: Operation theatre

Table 6: Distribution of surgeries as paired and single organ surgeries

	n (%)
Paired organs	419 (54.5)
Eyes	112 (14.6)
Ears and nose	57 (7.4)
Kidneys	104 (13.5)
Hands, legs and fingers	132 (17.2)
Breast	12 (1.6)
Ovaries	2 (0.3)
Single organs	125 (16.3)
Heart	5 (0.7)
Liver and pancreas	17 (2.2)
Uterus	103 (13.4)
Others	224 (29.2)

Table 7: Distribution of side marking for paired organs and other surgeries

	Side marking required (*n*)	Side marking done, *n* (%)
Paired organs	419	370 (88.3)
Eyes	112	101 (90.2)
Ears and nose	57	50 (87.7)
Kidneys	104	86 (82.6)
Hands, legs, and fingers	132	123 (93.2)
Breast	12	10 (83.3)
Ovaries	2	0
Others	154	117 (76)
Open	51	46 (90)
Laparoscopic	103	71 (70)

reported that, among the cases, in which SSM procedure was performed, 69% of cases were marked by the operating surgeons, while in 31% cases, it was delegated to nurse or junior doctors, who formed the surgical team but not always present in OT during incision.[14] In contrast to the findings of the above studies, Masud *et al*. reported that 99.6% of marks were made by the surgeons available in OT and all the marks were correct for location and laterality.[15]

In this study, in 36.1% of the patients, the SSM was visible within 6 inches from the incision site. This was less than that reported by Bathla *et al*. (55.6%)[14] and Masud *et al*. (59%).[15] Similarly, in this study, the crosses (27.7%), which are to be avoided, were the most commonly used signs. However, Bathla *et al*.[14] and Masud *et al*.[15] reported that arrows used in 25.7% and 88% cases, respectively, were the most commonly used signs. In addition, some surgeons had also used circles, written the name of procedure, and other combinations.[14]

A report by Minnesota Department of Health highlighted that the number of surgical adverse events increased steadily between 2014 and 2018, i.e., from 308 to 384. In 2018, the most frequently observed surgical adverse events, in decreasing order, were retained foreign object (*n* = 33), WSS (*n* = 24), and wrong procedure (*n* = 22). Among patients with WSS, 20% had no preoperative marking, in 20%, the team failed to visually confirm the marking, and in 12%, the team did not refer to the source document to clarify the procedure to be performed and site to be marked.[16]

In addition to the findings mentioned above, Bathla *et al*. reported that only 36.1% of the surgeons routinely performed the SSM procedures. SSM practice depended on the use of anesthesia (i.e., general or local anesthesia) in 13.9% of the surgeons and they marked 100% cases requiring local anesthesia. For surgeries involving laterality such as hernia repair, 100% and 92.3% surgeons marked open and laparoscopic procedures, respectively. It was also observed that >80% of surgeons did not mark the cases posted for surgeries involving single organ, perineal region, or when the exact nature of surgery was unknown before laparotomy or laparoscopy.[14]

Findings of this study mirror those observed by others.[14,16] In this study, surgical side marking was done on 88.3% of the surgeries performed on paired organs [Tables 6 and 7]. Other surgeries with laterality such as hernia repair, the marking was done in 90% when the open surgery was performed

and 70% for laparoscopic surgeries. In addition, it is worth highlighting that, in this study, only 15% and 19% of patients had no markings on their operating side and site, respectively.

In patients undergoing surgical procedures, infection of the surgical site is a common complication and patient's own skin flora is most commonly implicated.[17] Thus, to prevent the surgical site infections, the Centres for Disease Control and Prevention recommends the use of an appropriate antiseptic agent for preparing the skin.[18] It has been demonstrated that the agents used to prepare the skin commonly blur the markings, leading to difficulty in interpretation, or erases them completely. In this study, povidone-iodine and followed by betadine were used to prepare the surgical sites in 63.9% and 14.9% of the patients, respectively. Surgical sites were visible both before and after the site preparation in 63.2% and 46.5% of the patients, respectively. In a study, Mears *et al*. demonstrated that, compared to iodine-based agent (8%), chlorhexidine-based agent (42%) was more likely to erase the SSMs.[19] Similar findings were reported by Thakkar and Mears.[20] However, Mehendale *et al*. used henna as a marker which remained clearly visible in all the cases even after preoperative skin preparation with ethanol up to 8 days after application.[21]

Since the 1990s, various professional organizations have tried to address the issue of WSS and suggested protocols and checklists to be followed.[11,22,23]] However, application of these protocols and checklists have not resulted in the decline of the number of WSS.[24,25] In addition, according to the latest Sentinel Event statistics (2018),[6] there were 94 WSS and this was 95 in 2017. Thus, it is clear that efforts to curb the WSS have not been fruitful and there is a long way ahead.

Some hindrance to the successful utilization of these protocols is ignorance of the protocols, seniors inciting embarrassment or suppression, thinking that rechecking will result in loss of time, and use of a generic protocol that might be inappropriate for a particular specialty.[26] The surgeons must also be mindful that arrows and other symmetric signs may imprint on extremities as one part of the body presses on another such as arm, groin, and trunk, thus leading to transfer of signs to other body parts and resulting in perplexity and increased chances of WSS.[27,28]

As has been suggested by Bathla *et al*., operating surgeons are the ones responsible for this state of affairs, as many surgeons still firmly counter the mandatory SSM procedure of majority of the surgeries and believe that such procedures are not only unnecessary and unrealistic but also dangerous.[14] Thus, educating and changing the mindset of the surgeons is the initial step in preventing the WWS. Furthermore, in this study, 4.8% of the patients did not have the ID bands that could lead to identification errors. If the process is taken seriously by the surgeons, the compliance can be nothing <100%.

The limitations of the study are that it tries to capture the real findings in the OT of the hospitals involved and does not alter the practicing behavior of the operating surgeons or the operating teams involved. In addition, it is not known if the nurses or other individuals who had marked the surgical site were present in the OT at the time of surgery. Further, it is unknown if the markers used to mark the surgical site were of permanent or temporary nature. Furthermore, it remains unknown how many hospitals audited had specialty based or general SSM protocol in place.

Conclusions

Although WWS is rarely observed, the occurrence of a single event has immense implication on both the patient and operating surgeon. Thus, all the efforts should be directed in its prevention. The findings of this study demonstrate that SSM procedure is practiced in majority of the hospital audited, but a number of the operating surgeons involved in this procedure were far from desired. In addition, arrows with indelible permanent black marker pen pointing toward and near the actual site of operation should be made so that they remain after the skin is prepared for the operation, and the site of operation is draped. Finally, surgeons should be sensitized and educated and specialty-based protocols are to be framed so that they are strictly followed. There is a need to bring about national guidelines on the safe practice of SSM. Once protocols are in place and implemented, further audits will be required in future to assess their practice.

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