BACKGROUND

Surgical staplers, mechanical suturing, are mainly used to wound closure, organ or tissue resection, organ or tissue transection, and anastomoses in efficient and sterile manner [1]. Surgical staplers are generally made out of strong metals like stainless steel and titanium [2]. Strong metals were found to deliver staples with fewer rates of associated complaints [2]. The working principle of surgical staplers is basically inserting disposable cartridges to seal wounds. Figure 1 demonstrates the basic types of surgical staplers. The staplers could be used internally or externally in accordance with the surgical needs [3].

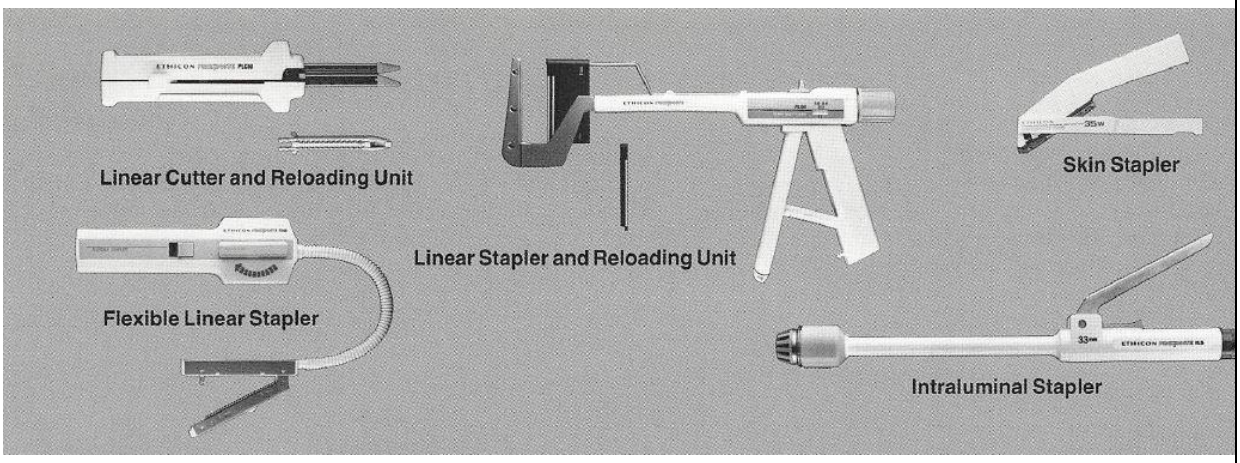

Figure 1. Basic types of surgical staplers [3]

However, there are some concerns regarding the safety of surgical staplers for internal use in an international level. A number of 21 reports of adverse events were received in the National Center of Medical Devices Reporting (NCMDR) database, which raised questions about the current practices at healthcare facilities in Saudi Arabia.

EVALUATION OUTCOMES

Part I: Methodology

An online survey approach was developed in order to evaluate the safety and performance of surgical staplers in Saudi healthcare facilities that have the device in question, as indicated by a previously conducted market analysis.

The survey questionnaire consisted of three main sections:

1- The first section included demographic questions.

2- The second section included complaints cases of surgical Staplers questions.

3- The third section included the awareness level of potential risks.

Part II: Results

In this part of the study, we present an analysis of the responses of surgical staplers' users to summarize the essential concerns found in the survey.

Complaints Cases of Surgical Staplers

Some of the survey questions were designed to discover issues encountered during surgery. Table 1. demonstrates the responses over seven common complications, which reported 2 adverse events, occurred using surgical staplers for internal use. The investigated list of complications were the most common complications in the NCMDR database, as reported in the risk analysis report:

- Stapler Jam
- Malformed staples
- Stapler not cutting
- Misfire
- No staple formation
- Partially stapling
- Locked on the tissue

Such complaints should be reported to the NCMDR if they are linked to surgical Staplers. Nevertheless, an investigation should be performed to figure out whether or not the adverse events, whenever confirmed, have been reported to the manufacturer and/or NCMDR, in accordance with what is mentioned in "Reporting and investigating adverse events and complaints of medical devices" within the Requirements for Post-Market Surveillance for Medical Devices (MDS-REQ 11) [4] . However, the received responses indicated a number of adverse events that had not been reported to SFDA nor the manufacturer.

Table 1: Adverse events according to the survey responses			
Complication	**Occurrence**	**Reported to SFDA**	**Reported to the manufacturer**
Stapler Jam	1	No	No
Malformed staples	0	NA	NA
Stapler cot cutting	0	NA	NA
Misfire	0	NA	NA
No staple formation	0	NA	NA
Partially stapling	0	NA	NA
Locked on the tissue	1	No	No

Awareness Level of Potential Risks.

Multiple elements need to be measured to reveal the comprehension of healthcare practitioner's community regarding the safety of certain medical devices, which are the awareness of potential risks of the device and the means to mitigate such threats. Nevertheless, figure 2, and as revealed by the Saudi users responses, demonstrates that 75% of Saudi users are aware of the published safety communication that highlighted potential risks of surgical staplers. The SFDA safety communication was published in reflection to the risk analysis report, to point out the devices' potential risks (Safety communication).

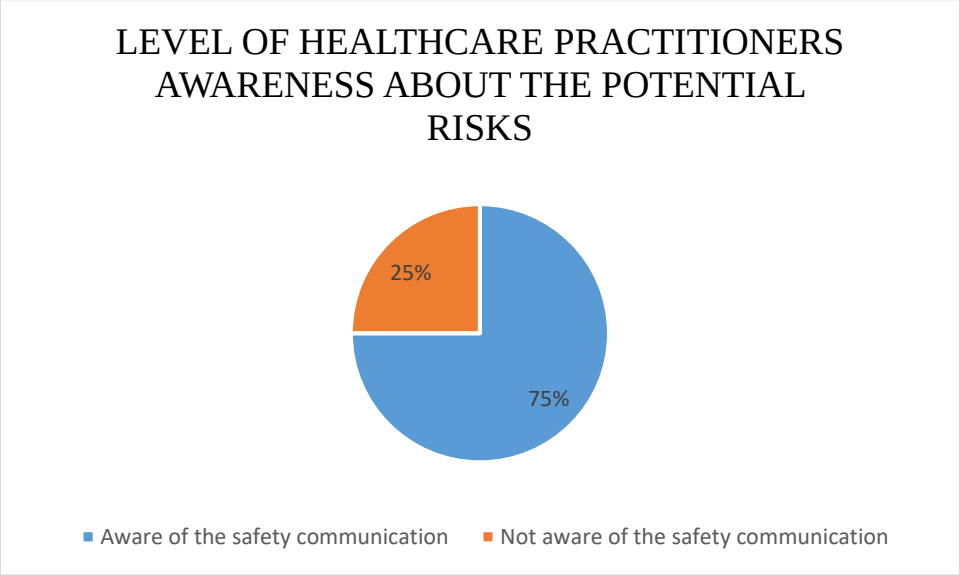

FIGURE 2. LEVEL OF HEALTHCARE PRACTITIONERS AWARENESS ABOUT THE SAFETY COMMUNICATION REGARDING THE RISKS ASSOCIATED WITH SURGICAL STAPLERS FOR INTERNAL USE.

Part III: Conclusion

The previous results and analysis provide indications of the actual practices of utilizing surgical staplers for internal use within the Saudi healthcare facilities. Such indications highlight primarily the following aspects:

I. Lack of adverse events reporting in patients with stapler jam and stapler locked on tissue, as these adverse events are not available at the NCMDR database.

II. Lack of the device user's awareness of the potential risks of the device, as indicated in the SFDA published safety communications.

SFDA RECOMMENDATIONS

After analyzing the responses of the device users in the Saudi market, the following set of actions are recommended:

i. Provide a plan to increase the awareness of the device users regarding the risks associated with the device and the proper practices to avoid adverse events.

ii. This plan is to be reviewed by the SFDA staff, and whenever approved, the manufacturer is committed to apply it in all sites that use the device in question.

iii. To encourage healthcare practitioners to report any complaints or adverse events they encounter with surgical staplers through the National Center for Medical Devices Reporting (NCMDR) system: https://ncmdr.sfda.gov.sa, the Saudi Vigilance System https://ade.sfda.gov.sa, or the SFDA call center: 19999

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