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INTRAUTERINE TAMPONADE BALLOON COMPLICATIONS IN MAUDE DATABASE: A CRITICAL ANALYSIS

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ABSTRACT

Introduction: Intrauterine tamponade balloons (IUTBs) are employed in the management of postpartum hemorrhage (PPH), particularly in cases of uterine atony, to reduce the need for surgical interventions such as hysterectomy or uterine artery embolization. However, their use may be associated with adverse outcomes. This study aims to evaluate adverse events (AEs) related to IUTBs reported in the MAUDE (Manufacturer and User Facility Device Experience) database, focusing on device malfunctions, patient complications, and manufacturer involvement. **Methods:** A retrospective review was conducted using MAUDE database entries from January 1, 2020, to November 25, 2024. Reports referencing IUTBs were identified, extracted, and categorized according to device issues, patient-related complications, manufacturer data, and device classification codes. Descriptive statistics were used to summarize reporting trends and outcomes. **Results:** A total of 901 AE reports involving IUTBs were identified. Device malfunctions constituted over half the cases (507/901). The most frequently reported device issue was "Adverse Event Without Identified Device or Use Problem" (400/901). The most commonly reported patient-related outcome was "No Clinical Signs, Symptoms, or Conditions" (306/901). COOK INC was identified as the manufacturer in 419 reports. The device code K170622 was cited in 400 cases. Affected anatomical areas included the uterus, cervix, and vagina. **Conclusion:** AE data suggest that while IUTBs are a valuable tool in the management of PPH, complications related to device malfunction and inconsistent patient outcomes warrant further attention. Limitations such as potential underreporting and incomplete entries reduce the granularity of MAUDE data; however, it remains a crucial source for post-market surveillance. Improved device training and reporting practices are essential to ensure safe and effective use of IUTBs.

KEYWORDS: MAUDE, Adverse events, Intrauterine tamponade balloon.

INTRODUCTION

Medical devices play a vital role in modern healthcare, supporting the diagnosis, prevention, monitoring, and treatment of a wide range of conditions.[1] These devices range from simple instruments such as syringes and thermometers to more complex technologies including implantable contraceptive systems and intrauterine devices (IUDs). An IUD is a small, T-shaped medical device inserted into the uterus for long-term contraception, designed to prevent fertilization through mechanisms such as sperm inhibition, endometrial alteration, or hormone release.[1-3]

Unintended pregnancies remain a significant global public health concern, contributing to maternal morbidity and socioeconomic burden.[4] Long-acting reversible contraceptives (LARCs), particularly IUDs, have emerged as highly effective solutions due to their long duration of action, reversibility, and minimal user dependency.[5,6] IUDs are broadly classified into copper-containing devices and hormone-releasing systems, both of which have demonstrated high efficacy rates and favourable safety profiles.[7,8] Despite these advantages, IUD use is not without risks, as complications such as device expulsion, uterine perforation, infection, and abnormal bleeding have been reported.[9-10]

The Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the U.S. Food and Drug Administration (FDA), serves as an essential post-marketing surveillance system that collects reports of medical device–related adverse events (AEs) from manufacturers, healthcare professionals, and consumers.[1] Evaluation of MAUDE data enables identification of real-world safety concerns, device malfunctions, and patient outcomes that may not be fully captured in pre-marketing clinical trials.[11]

Recent analyses of IUD-related AEs indicate that device issues such as leakage, material rupture, device dislodgement, and procedural complications contribute significantly to reported cases. Patient outcomes range from asymptomatic presentations to serious conditions including haemorrhage, uterine perforation, and coagulation disorders, highlighting variability in clinical impact. Additionally, reporting trends suggest that a substantial proportion of events require medical intervention, emphasizing the need for improved monitoring and reporting systems.[12-14]

Given the increasing utilization of IUDs worldwide, continuous evaluation of their safety profile is crucial. This study aims to systematically analyse AEs associated with intrauterine devices reported in the MAUDE database, with a focus on identifying common device-related issues, patient outcomes, and reporting patterns. Such insights are essential to enhance patient safety, inform clinical decision-making, and guide improvements in device design and regulatory policies.

METHODS

A retrospective analysis was conducted using the MAUDE database to identify reports associated with IUDs. Reports submitted between January 1, 2020, to November 25, 2024, were retrieved to capture a comprehensive range of device-related AEs over time. The search strategy incorporated relevant device product codes along with keywords such as “intrauterine device,” “IUD,” “copper IUD,” and “hormonal IUD” to ensure inclusion of all pertinent cases.

Each report was systematically reviewed and categorized based on the type of AEs, including device-related issues and patient-related outcomes. Device problems were classified into categories such as leakage, material rupture, device dislodgement, inflation or insertion-related issues, and cases without an identified device or use problem. Patient outcomes were grouped into clinically relevant categories, including no symptoms, hemorrhage or bleeding, uterine perforation, coagulation disorders, hypotension, and other reported complications. Treatment interventions, where available, were also documented.

Additional variables extracted included patient demographics (age group), event type (malfunction, injury, or death), geographic distribution of reports, device availability for evaluation, and whether the device was returned to the manufacturer. Reporter occupation (e.g., physician, nurse, pharmacist, or other healthcare professional) was also analysed to assess reporting patterns.[11]

Descriptive statistical methods were used to summarize the frequency and distribution of AEs, device-related problems, and patient outcomes. Trends were evaluated across demographic categories and reporting characteristics to identify patterns in IUD-related complications and to provide insights into real-world device safety.

RESULTS

A total of 901 AE reports related to intrauterine tamponade balloons (IUTBs) were identified from the MAUDE database during the study period. Among these, injury-related events (n = 239) were slightly more frequent than device malfunctions (n = 209), while fatal outcomes were rare (n = 2) as shown in Figure. 1.

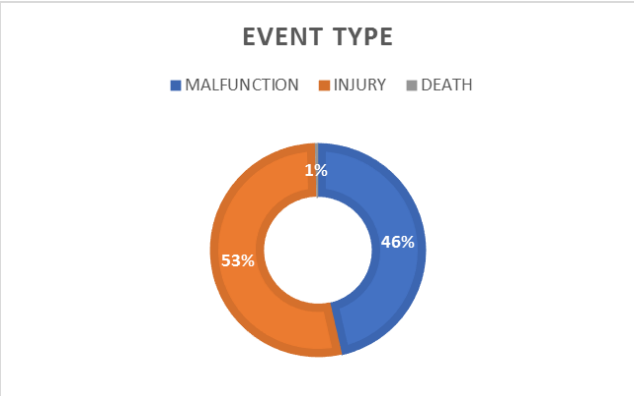

Figure 1: Event Type.

Device-related issues were commonly reported, with the highest proportion categorized as “Adverse events without an identified device or use problem” (n = 400). Among specific malfunctions, “fluid or blood leak” (n = 237) was the most frequently observed, followed by “material rupture” (n = 46), “inflation problems” (n =

27), and "device or component detachment" (n = 15). Other issues such as suction failure, procedural errors, and missing components were reported less frequently as shown in Table.1.

Table 1: Device Problem.

Device Problem	Count
Adverse Event Without Identified Device or Use Problem	400
Fluid/Blood Leak	237
Material Rupture	46
Inflation Problem	27
Detachment of Device or Device Component	15
Fluid/Blood Leak; Material Puncture/Hole	9
Improper or Incorrect Procedure or Method	9
Suction Failure	9
Component Missing	9
Leak/Splash	9
Device Dislodged or Dislocated	7
Suction Problem	7

In terms of patient-related complications, hemorrhage or bleeding (n = 213) was the most commonly documented clinical problem. However, a substantial number of reports indicated no clinical signs or symptoms (n = 381) or insufficient information (n = 192), reflecting limitations in reporting completeness. Serious complications such as disseminated intravascular coagulation (n = 20), uterine perforation (n = 16), and lacerations (n = 14) were also noted, along with less frequent events including hypotension, thrombosis, and coagulation disorders as shown in Table.2.

Table 2: Patient Problem.

Patient Problem	Count
No Clinical Signs, Symptoms or Conditions	381
Hemorrhage/Bleeding	213
Insufficient Information	192
Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	119
No Consequences Or Impact To Patient	62
Disseminated Intravascular Coagulation (DIC)	20
Uterine Perforation	16
Laceration(s)	14
No Known Impact Or Consequence To Patient	12
Blood Loss	9
Foreign Body In Patient	8
Low Blood Pressure/ Hypotension	8
Fever	6
Thrombosis/Thrombus	6
Coagulation Disorder	4

Regarding patient outcomes, the majority of cases required medical or procedural intervention (n = 163), while other outcomes included unspecified events (n = 125), hospitalization with intervention (n = 41), and combined outcomes such as intervention with disability (n = 17). Life-threatening events were reported in 7 cases, indicating a small but clinically significant proportion of severe outcomes as shown in Table.3.

Table 3: Patient Outcome.

Patient Outcome	Count
Required Intervention	163
Other	125
Hospitalization; Required Intervention	41
Other; Required Intervention	38
Required Intervention; Disability	17
Hospitalization	10
Life Threatening	7
Required Intervention; Hospitalization; Other	7
Other; Hospitalization	7

Management strategies reported in the dataset primarily involved uterotonic agents such as methylergometrine and oxytocin, often used in combination with other therapies including tranexamic acid, carboprost, and blood transfusion as shown in Table.4.

Table 4: Management strategies.

Treatment	Count
Methergine (Methylergometrine Maleate).; Pitocin [Oxytocin] (Oxytocin).	4
Cytotec; Hemabate; Methergine; PRBC ; TXA	2
Hemabate (Carboprost Trometamol).; Methergine (Methylergometrine Maleate).; Pitocin [Oxytocin] (Oxytocin).; Tranexamic Acid (Tranexamic Acid).	2
Syringe, Sterile Water/Saline	2

Demographically, most cases were observed in patients aged 21–30 years, followed by those aged 31–40 years, with fewer cases reported in other age groups as shown in Figure.2.

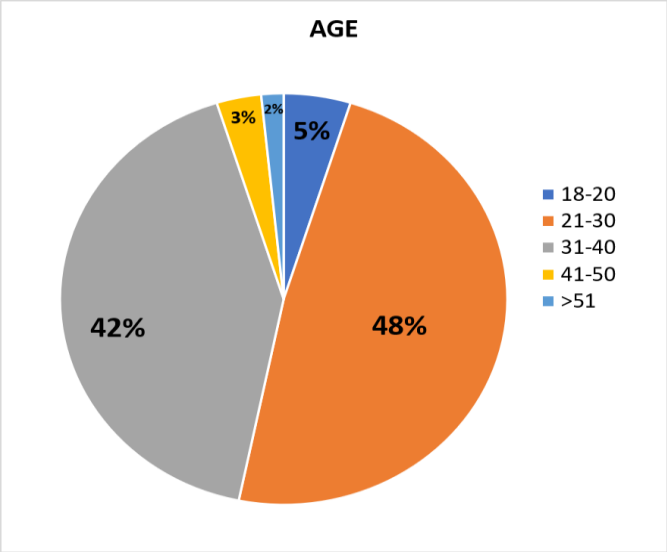

Figure 2: Demographics.

Reports were most frequently submitted by other reporters (n = 325) and physicians (n = 275), followed by nurses and other healthcare professionals as shown in Figure.3.

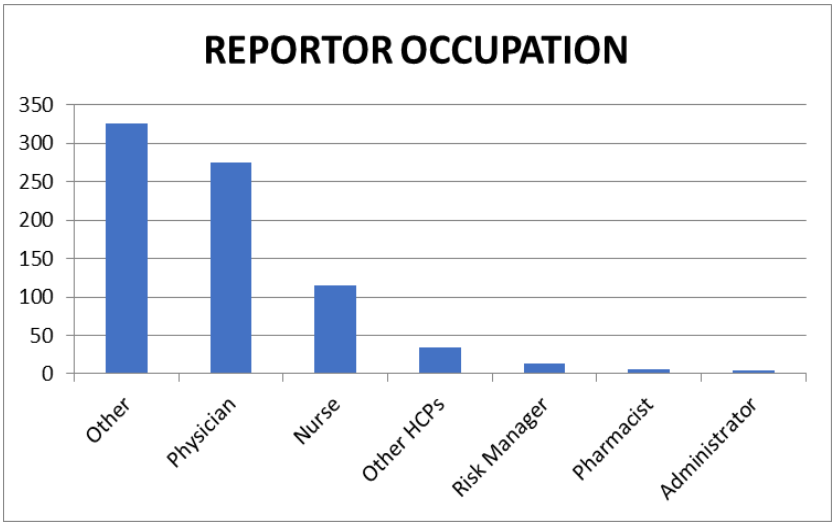

Figure 3: Reporter Occupation.

Geographically, the majority of reports originated from the United States (n = 448), with relatively few cases reported from other countries as shown in Figure.4.

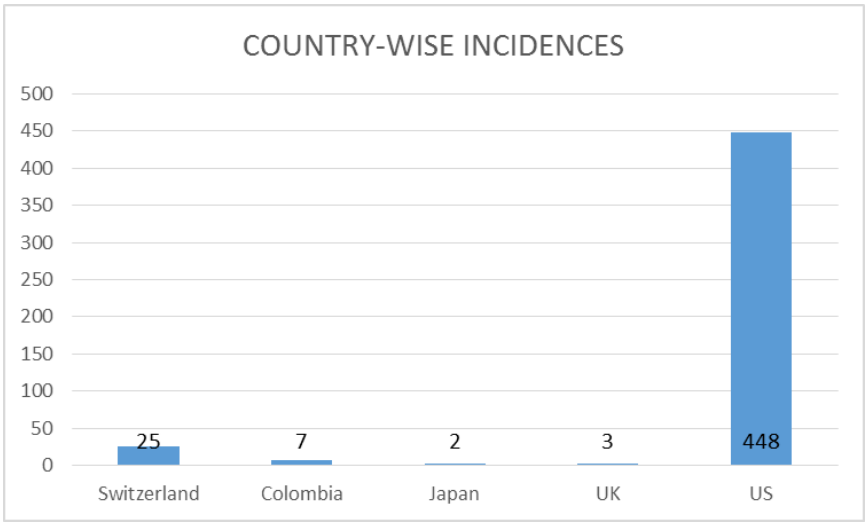

Figure 4: Country-wise Incidences.

In terms of device evaluation, most devices were not returned to the manufacturer (n = 414), and product problems were reported in a large proportion of cases (n = 706) as shown in Figure.5.

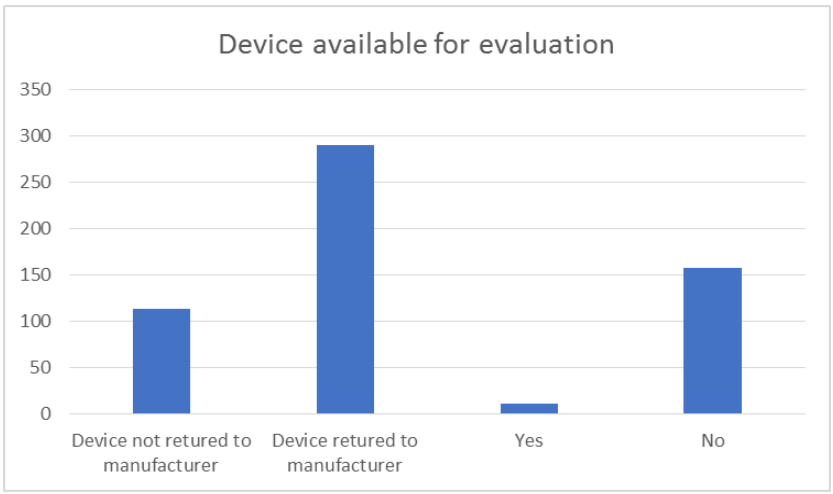

Figure 5: Device evaluation.

Additionally, most devices were intended for single use, reflecting their standard clinical application as shown in Figure.6. Overall, the findings highlight a predominance of device-related issues and bleeding complications, with a considerable proportion of cases requiring clinical intervention.

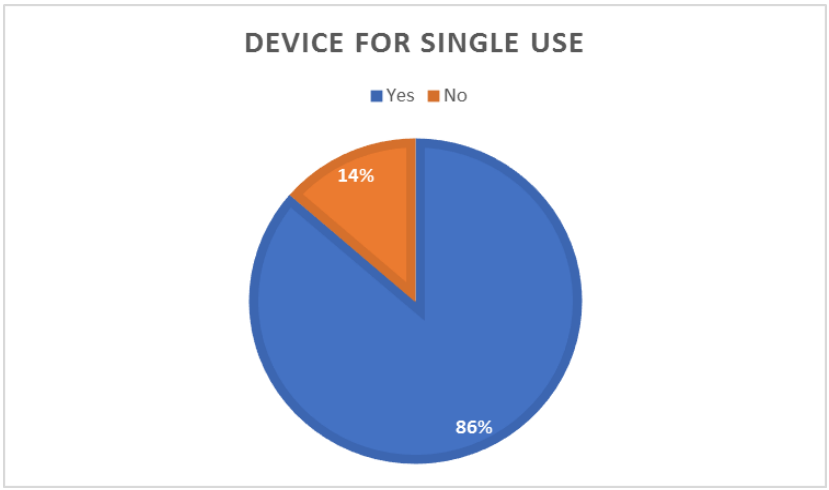

Figure 6: Device for single use.

DISCUSSION

The present analysis of 901 AE reports related to IUTBs from the MAUDE database provides important insights into the safety profile and real-world performance of these devices in the management of postpartum hemorrhage (PPH). The findings demonstrate that although IUTBs are widely regarded as effective, minimally invasive alternatives to surgical interventions, they are not without complications, particularly when used in complex clinical scenarios or without optimal technique.

A key observation from this study is the higher proportion of injury-related events compared to device malfunctions, with hemorrhage or bleeding emerging as the most frequently reported patient-related complication. This aligns with the primary indication of IUTBs in PPH management, where persistent bleeding may reflect either treatment failure or severe underlying uterine atony. Previous studies have reported that uterine balloon tamponade achieves high success rates in controlling hemorrhage; however, reduced effectiveness has been observed in cases complicated by coagulopathy, infection, or delayed intervention.[12,13,16] The occurrence of serious complications such as disseminated intravascular coagulation (DIC) and uterine perforation further emphasizes the importance of early intervention, appropriate patient selection, and adherence to standardized protocols.[15-17]

Device-related issues, particularly fluid or blood leaks, were among the most commonly reported malfunctions in this study. These findings may indicate limitations in device integrity, incorrect placement, or user-related factors. The effectiveness of IUTBs is highly dependent on adequate intraballoon pressure to achieve tamponade of uterine vessels; therefore, leakage or improper inflation can significantly compromise therapeutic outcomes. Previous systematic reviews and clinical studies have similarly highlighted that inadequate pressure generation and device-related failures contribute to unsuccessful hemorrhage control.[14,18-21] Additionally, the high proportion of reports categorized as “adverse events without identified device or use problem” reflects the inherent limitations of passive surveillance systems such as MAUDE, where detailed clinical context and causality assessment are often lacking.

The majority of patients in this study required clinical intervention, with a subset experiencing hospitalization or life-threatening outcomes. These findings are consistent with existing literature indicating that while IUTBs can reduce the need for invasive surgical procedures such as hysterectomy, they should not be considered a definitive standalone therapy. Instead, they are most effective when integrated into a comprehensive PPH management strategy that includes uterotonics, antifibrinolytics, fluid resuscitation, and timely escalation to surgical interventions when necessary.[15,19] Current guidelines emphasize a stepwise, multimodal approach to PPH management, which is supported by the treatment patterns observed in this dataset.[22]

Another important observation is the substantial proportion of reports with incomplete clinical information or absence of documented symptoms. This highlights a significant limitation of the MAUDE database, which is subject to underreporting, reporting bias, and variability in data quality.[1,23-25] Furthermore, the fact that a large number of devices were not returned to manufacturers limits the ability to conduct detailed technical evaluations, thereby restricting the identification of specific device-related failure mechanisms. These limitations underscore the need for improved reporting standards and more robust post-market surveillance systems.

The predominance of reports from the United States likely reflects more stringent reporting requirements and greater awareness of device surveillance systems rather than a true higher incidence of AEs. This suggests that underreporting may exist in other regions, highlighting the importance of developing standardized global reporting frameworks to ensure a more accurate assessment of device safety across diverse healthcare settings.[26]

Overall, this study reinforces that while IUTBs remain a valuable and often life-saving tool in the management of PPH, their use is associated with a spectrum of complications ranging from minor device issues to severe clinical outcomes. Ensuring proper training, correct insertion techniques, adequate intraballoon pressure maintenance, and close patient monitoring are essential to optimize outcomes. Future prospective studies, along with enhanced surveillance and reporting mechanisms, are necessary to better define the risk–benefit profile of these devices and to inform evidence-based clinical practice.

CONCLUSION

IUTBs are valuable devices for managing postpartum hemorrhage and can help reduce the need for more invasive procedures. However, analysis of MAUDE reports shows that their use is associated with several AEs such as bleeding-related complications and device leakage. While most cases can be successfully can be managed with medical intervention, some can result in serious outcomes such as uterine perforation, DIC, and other life-threatening complications. These findings emphasize the importance of proper device use, clinician training, and close patient monitoring. Improved AE reporting and continued post-market surveillance are also needed to better understand device performance and enhance patient safety. Overall, IUTBs remain an important device for PPH management, but ongoing surveillance is required to ensure their safe and effective use.

REFERENCES

1. U.S. Food and Drug Administration. Manufacturer and User Facility Device Experience (MAUDE) database.
2. World Health Organization. Medical device technical series: Definitions and classifications. Geneva: WHO.
3. Dean G, Goldberg AB. Intrauterine devices: mechanisms and use. *UpToDate*.
4. World Health Organization. Unintended pregnancy and reproductive health. Geneva: WHO.
5. Adusumilli PK, Begum F, Sangnure AA, George J. Antibiotics-induced pulmonary embolism: A disproportionality analysis in Food and Drug Administration database of Adverse Event Reporting System using data mining algorithms. Perspect Clin Res., Jan-Mar. 2025; 16(1): 44-49. doi: 10.4103/picr.picr_10_24. Epub 2024 Sep 13. PMID: 39867523; PMCID: PMC11759233.
6. Winner B, Peipert JF, Zhao Q, et al. Effectiveness of long-acting reversible contraception. *N Engl J Med*., 2012; 366(21): 1998–2007.
7. George J, Dsouza PL, Yalamanchili Jahnavi, Singh H, Kumar PA. Databases and Tools for Signal Detection of Drugs in Post-Marketing Surveillance. CRC Press eBooks, Aug. 14, 2024; 32–43.
8. Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use. *MMWR Recomm Rep*., 2016; 65(3): 1–103.
9. George, Jeesa; Kumar, Adusumilli Pramod; Kalaiselvan, Vivekanandan, et.al; Development and validation of a standardized causality assessment tool for adverse events associated with medical devices. Perspectives in Clinical Research ():10.4103/picr.picr_153_25, February 28, 2026. | DOI: 10.4103/picr.picr_153_25
10. Heinemann K, Reed S, Moehner S, et al. Comparative safety of intrauterine devices. *Contraception*, 2015; 91(4): 280–283.
11. George, J., Kumar, A.P., Shynu, N.E. et al. Adverse Events Linked to Dental Devices: An In-depth Analysis of the Manufacturer and User Facility Device Experience Database. Biomedical Materials & Devices, 2025. https://doi.org/10.1007/s44174-025-00603-y
12. Thiery M. Intrauterine contraception: history and development. *Eur J Obstet Gynecol Reprod Biol*., 2000; 90(2): 145–152.
13. George, Jeesa; Kumar, Adusumilli Pramod; Kalaiselvan, Vivekanandan, et.al; Development and Validation of Kap Questionnaire on Materiovigilance among Dental Professionals- A Pilot Study. African Journal of Biomedical Research, 2025; 28(3S): 960-968. https://doi.org/10.53555/AJBR.v28i3S.8208
14. Andersson K, Ryde-Blomqvist E, Lindell K, et al. Perforations with intrauterine devices. *Contraception*, 1998; 57(4): 251–255.
15. Braaten KP, Benson CB, Maurer R, et al. Malpositioned intrauterine devices. *Obstet Gynecol*, 2012; 119(5): 1014–1020.
16. Heinemann K, Barnett C, Reed S, et al. Risk of uterine perforation with IUD use. *Lancet*, 2015; 385(9981): 2441–2447.
17. World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: WHO, 2012.
18. Doumouchtsis SK, Papageorghiou AT, Arulkumaran S. Systematic review of conservative management of postpartum hemorrhage: what to do when medical treatment fails. *Obstet Gynecol Surv*, 2007; 62(8): 540–547.
19. Tindell K, Garfinkel R, Abu-Haydar E, et al. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review. *BJOG*, 2013; 120(1): 5–14.
20. Georgiou C. Balloon tamponade in the management of postpartum haemorrhage: a review. *BJOG*, 2009; 116(6): 748–757.
21. Burke TF, Ahn R, Nelson BD, et al. A postpartum hemorrhage package with condom uterine balloon tamponade: a prospective multi-center case series in Kenya, Sierra Leone, Senegal, and Nepal. *BJOG*, 2016; 123(9): 1532–1540.
22. Weeks AD. The prevention and treatment of postpartum haemorrhage: what do we know, and where do we go to next? *BJOG*., 2015; 122(2): 202–210.
23. Suárez S, Conde-Agudelo A, Borovac-Pinheiro A, et al. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis. *Am J Obstet Gynecol*, 2020; 222(4): 293.e1–293.e52.
24. Kumar, A. P., S, J., A V, K., & George, J. Study on the impact of sensitization on materiovigilance programme among pharmacy and dental postgraduate students. Expert Review of Medical Devices, 2024; 21(6): 543–552. https://doi.org/10.1080/17434440.2024.2364821
25. Sentilhes L, Vayssière C, Deneux-Tharaux C, et al. Postpartum hemorrhage: guidelines for clinical practice. *J Gynecol Obstet Hum Reprod*, 2017; 46(10): 117–131.
26. Hauser RG. Here we go again—failure of postmarketing device surveillance. *N Engl J Med*., 2012; 366(10): 873–875.