Identifying Condom Catheter Component to Optimize Its Function As Intrauterine Balloon Tamponade (Iubt): A Laboratory Test

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Abstract

Uterine atony is the primary cause of postpartum hemorrhage worldwide. Further management for severe bleeding or limited uterotonic is the insertion of intrauterine balloon tamponade (IUBT), and a modified condom catheter is the most affordable form of IUBT. However, it has some limitations that can emerge from the component of the tools. This study aims to identify the equipment component of the condom catheter and discover potential improvements to optimize its function as IUBT. Preclinical research under laboratory environmental conditions was conducted. Five condom types, six catheter sizes, and a type of macro drip IV tubing were included in the study. The specifications of all condoms were almost similar and did not significantly differ in capacity, shape, and leakage. The condom shapes were more rounded and had a high possibility of filling the uterine space entirely if tied in the middle instead of close to the tip based on the standard. There was no significant time difference ($p = 0.111$; CI95% 3.31–3.52) in draining the fluid when using large catheters (nos 18F, 20F, 22F, and 24F) and removing the catheter. However, not using a catheter should consider the device's required length and mother's comfort in early mobilization. Also, further clinical studies are highly recommended.

Introduction

Hemorrhage still dominates as the leading cause of maternal mortality worldwide (27.1%), and more than two-thirds are classified as postpartum hemorrhage (PPH)[1]. Most primary PPH cases were caused by uterine atony[2], the myometrium's failure to adequately contract and retract as a response to endogenous oxytocin after delivery[3]. Consequently, the open arteries are not properly pinched, which can then cause bleeding.

The World Health Organization (WHO) recommended the following steps for uterine atony management. The first line uses uterotonics. However, if mothers do not respond to the treatment or if uterotonics are unavailable, the next recommendation is using intrauterine balloon tamponade (IUBT)[4,5]. The mechanism of IUBT is to halt bleeding by applying pressure to uterine arteries and stimulating uterine contraction until hemostasis is achieved[6,7]. In some regions, IUBT sets have been modified to various types.

Generally, there are two main sorts of IUBT: the purpose-designed IUBT such as Bakri balloon, BT-Cath, and ebb balloon and the modified IUBT from other available equipment such as Foley catheter, Rusch balloon, condom catheter set, and Sengstaken–Blakemore tube[8,9]. However, the set of condom catheters is identified as the cheapest and simplest, and effective form of IUBT for PPH[10,11]. It merely consists of a condom, a urinary catheter, and an Intravenous (IV) tubing[6,12]. So, it is widely used, particularly in resource-poor settings[10,11]. Nevertheless, compared with the purpose-designed and costlier IUBTs, such as the Bakri balloon, condom catheters required a significant bit longer time to halt hemorrhage[13], although both have similar effectiveness. Moreover, Anger[14] reported that introducing a condom catheter did not improve maternal outcomes and was associated with an increase in combined incidence of PPH-related surgery and maternal death.

More studies are needed to determine the predictors of IUBT failure[15], and some of them are related to the tools and components used[14,16]. However, most studies only compared IUBT types and have not yet explicitly explored the condom catheter equipment set whereas there are various types of condoms and catheters that may affect their purpose when using as IUBT. Besides, the recommended equipment such as catheter size nos 24F is not always in the maternal ward. A study then attempted to remove the catheter as a component[17] but has not been

studied further and compared with the standard protocol. Hence, this research specifically analyzed several critical aspects of the condom catheter component and attempted to discover the potential amelioration to optimize its function as IUBT.

Methods

This research is a preclinical or nonclinical test, which includes a series of experiments by testing some examined items under laboratory environmental conditions to obtain data on their nature and safety concerning human health and/or the environment[18]. A series of experiments were conducted in the Midwifery Program Laboratory of Universitas Gadjah Mada from April to October 2019. The Ethics Commission of the Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, approved the ethical clearance.

This study examined five brands of condoms, six sizes of catheters, and a type of macro drip IV tubing that were readily available on the market in Indonesia. The condom brands were Andalan, BKKBN, Durex, Fiesta, and Sutra. The catheter sizes were nos 14F, 16F, 18F, 20F, 22F, and 24F, which were similar to the brand Rusch. The IV tubing used one type of GEA brand with specification macro drip (1 ml = 20 drops), Ø 4.1 mm, and length 150 cm. A checklist sheet was used to collect data, which were then analyzed descriptively.

The aspects tested for the condoms were specifications, shape/form, maximum capacity (volume), and leakage, while for the series of catheter and IV tubing was flow velocity and length. Condom specifications consisted of the material, length, width, and texture. These were identified as written in the inner box of the condom, which were provided by the manufacturers.

To test the shape, volume, and leakage, the condom installation technique was used following the standard operating procedure from the health maternal guideline[19]. Every condom was tested three times in similar conditions through the following steps: (1) labeling every condom, (2) inserting the catheter into the condom, (3) tying the condom to the catheter using a 10 cm string at 3cm from the tip of the condom, (4) connecting the catheter to the macro drip IV tubing and infusion bottle, (5) placing the condoms on a flat table, (6) simultaneously streaming the fluid infusion by releasing the clamp, (7) starting fluid infusion by 500 mL until the maximum clinical volume based on theory (5000 mL) is reached[9], and (8) having left idle for 2 x 24 hours.

Furthermore, after scrutiny the form of the condom, we attempted to move the knot and found differentiation shapes if the condom is tied in the middle (Table 1). We then selected this type for comparison with the standard-compliant tying site. Hence, there were two kinds of knot place (Fig. 1): (a) near the tip of the condom (3 cm) based on the standard and (b) in the middle of the condom.

For catheter testing, flow velocity was compared using six catheter sizes and when removing the catheter from the component (only when using an IV tubing). The test was conducted six times for each type of catheter and no catheter in a similar condition. We arranged infusion pole height to maximum height (200 cm), and its height from the top of the edge delivery bed was 130 cm considering the fixed delivery bed height was 70 cm. Equalization of the infusion pole height was intended to avoid bias in the measurement of appropriate device length as well as flow velocity caused by gravity-fed differences[20]. The flow velocity data were summarized in descriptive statistics and then analyzed using the Analysis of Variance (ANOVA) test with SPSS. Besides, we

examined the length of the device using either a catheter or an IV tubing only by a measuring tape and then analyzed descriptively.

Results

In this research, the aspects used for condom testing were the specifications (material, length, width, and texture), shape, capacity, and leakage. Data are presented in Table 1.

All five condoms generally looked similar in shape when they were tested under the same situation, based on either the volume or knot site types. At 500–1000 mL filling, the shapes of the condoms were different based on knot site between (a) 3 cm from the tip and (b) in the middle of the condom. The condom shape looked oval with a rounded base and tapered off at the end in type (a) and seemed rounded in almost all the parts in type (b). The condom's shape in both knot site types gradually changed as the liquid was added. At 3000 mL filling, the form of the condoms commenced to looked similar (rounded on all sides). However, the condoms appeared to be elongated in a knot site (a) and stretched in a knot site (b).
For capacity and leakage, although the five condom types have different specifications, especially on the length, all condoms showed the same capacity and did not experience leakage and breakage in the 2 × 24-h. The condition was applied in all types of condoms, volume, and knot sites.

Furthermore, catheter and IV tubing testing as a series of components consisted of flow velocity and the device length, which were tested in the height of infusion pole 130 cm from the top of the edge delivery bed. Table 2 presents the catheters' ability to drain fluid per 500 mL based on the catheter size.

As shown in Table 2, the fastest catheter to drain per 500 mL fluid was no. 24F (3.20 min), followed by no catheter (3.30 min), and the slowest was no. 14F (5.40 min). Based on ANOVA statistical analysis, significant differentiation was noted in all catheter types ($p = 0.001$). Moreover, no discrepancy was found statistically on testing catheter nos 18F, 20F, 22F, and 24F and no catheter ($p = 0.111$).

Besides, all types of urinary catheters used in this study had similar lengths (40 cm), whereas the length of the IV tubing was 150 cm, so if they were assembled, the total length was 190 cm.

Discussion

Condom catheter as IUBT was first introduced in 2001 by Professor Sayeba Akhter, an obstetrics-gynecologist from Bangladesh[6]. It has been included in the WHO recommendation because of its effectiveness, simplicity, and cheapness, particularly for resource-poor settings[10]. However, several studies showed the limitation of condom catheters when used as IUBT[13,14], and it can be from the component of the tools[14,16]. This study attempted to identify some substantial aspects of a condom catheter component that can affect its function as IUBT. It then attempted to discover the potential improvement.

Condom

Condom is the primary tool of the component that functions like a balloon for suppressing the uterine vessels and stimulating uterine contractions[6]. However, various types of condoms based on the materials, sizes, and textures can influence their function as IUBT. The international standard for condoms is specified in ISO 4074:

Natural Latex Rubber Condoms—Requirements and Test Methods. As a partner ISO, the WHO broadened the guideline in the Male Latex Condom: Specification, Prequalification, and Guideline for Procurement (revised 2013).

All the condoms used in this study were made of natural latex materials. Another material used for condoms is synthetic rubber such as polyurethane, but high-quality natural latex is the primary recommendation of the WHO. It provides a preferential combination of sensitivity, strength, and elasticity[21]. However, 4% of the general population and 7.2% of susceptible patients have an allergy to latex[22]. There are two types of potential responses to latex allergy: immediate reaction (Type I) and delayed hypersensitivity (Type IV). The most common symptom of the first type is a skin rash (contact dermatitis) and of the second type is respiratory problems, which can lead to anaphylaxis in an extreme case. Besides, condom allergy may also be due to accelerator residues, color, fragrance, flavor, or concomitant use of pleasure enhancer and local anesthetics[21,22]. Hence, although studies reporting allergic reactions in using latex condoms as IUBT are lacking, the guideline should consider ensuring that patients do not have a latex allergy through careful anamnesis before placement. If possible, synthetic rubber condoms made from polyurethane should also be provided in health services as alternative and replacement for natural latex condoms for latex allergic patients. The polyurethane or silicone material is proven safe and has been vastly used by manufacturers to make the purpose-designed IUBT, such as Bakri, BT-Cath, and ebb tamponade[8].

Condom sizes are classified as wide or narrow, and there is no condom with fixed differentiation size, even in developed countries. The sizes most commonly marketed are 49 and 53 mm. Thinner condoms measure 47–50 mm and wider ones 51–54 mm[21]. Although narrower condoms are preferred in Asian countries, this study found that most condoms were wider (> 50 mm). The standard length of condoms is 165–190 mm, measured from the open end to the tip (excluding any reservoir). This study showed that the length of condoms is approximately 178–190 mm. There is no significant implication in choosing condom size. All condom sizes in this study presented similar results both in shape and capacity.

The surface of condoms can be textured or nontextured. Typically, texture consists of several ribs or dots formed onto the condoms' surface. In this study, we identified three nontextured condoms, and two have ribbed and dotted textures. Like the length and width, the texture did not affect either the shape or capacity of the condoms. However, a recent study reported that the texture of condoms is not rigid enough, and they often slip out from the uterine cavity[23]. Although the condition can prevent packing rolled gauze into the vagina[4,19], use of textured condoms may also be further investigated to solve this problem.

For the condom’s shape, since it was first used, the conventional parallel-sided (cylindrical) shape has been in the WHO specification[21]. A condom was used as IUBT because of its ability to inflate like a balloon. Its form is close to previous IUBT concepts, such as Bakri balloon, Sengstaken–Blakemore tube, and Rusch balloon. However, Georgio reported that the forms of all IUBT types are different, especially when they are filled with fluid. Generally, the balloon form depends on the device's design, such as presence of a drainage channel, which can affect adjustment between balloon to the surface of uterus[8].

The balloon's shape is vital as it has implications for filling the uterine space as the working principle of IUBT in handling uterine atony. Darwish[13] showed that condom catheters required more extensive time than Bakri balloons in reaching hemostatic conditions. It might be caused by several factors, such as the balloon shape. In

principle, the balloon must inflate the uterus from the inside to provide direct compression to the uterine vessels and stimulate uterine contraction[6,7]. As uterine muscles contract, the open blood vessels will soon close, and then, bleeding can stop[24,25]. Conversely, if the balloon's shape cannot fill the entire uterine space, the balloon's function cannot be optimal in suppressing the blood vessels and stimulating uterine contraction. Therefore, to attain optimal condition, a balloon should be flexible to adjunct the uterus' shape. Typically, the uterus has a pear-shaped structure (pyriform)[26], and after delivery, it tends to be oval and in an angulated and retroverted position[27].

As the effectiveness of IUBT correlates with uterus shape changes and balloon-endometrial interaction[28], several types of balloon tamponade were designed or modified to conform to the uterus configuration. For example, BT-Cath was formed with an inverted pear shape, which is suitable to the uterine cavity's structure. For modified IUBT that has a drainage channel like the Sengstaken–Blakemore balloon, its tip is usually cut, or the distal gastric balloon is folded back to fit between the uterine fundus and balloon[8]. In this study, we tried changing the knot site to the standard to optimize the shape of the condom balloon.

Figure 2. illustrates that the tying site in the middle of the condom (b) is closely similar to the uterine shape and potentially filling the entire uterine cavity than the standard tying site (a) on the all-fluid filling conditions. In contrast, because the standard knot site produces an inverted pear shape with a tapered top (a), there is a part of the uterine cavity, especially at the fundus, where the balloon cannot fully compress then causes bleeding.

Moreover, Wang[15] showed that one of the failure causes of IUBT is the over-expanded lower uterine segment (LUS) due to prolapsed IUBT or over-distended uterus in case of multiple pregnancies or overweight infant. Related to this, balloon with a wider bottom then potentially worsens LUS enlargement. Therefore, although it needs further research in vitro condition, it can be noted that knot placements on the condom had a significant improvement.

The capacity of the balloon tamponade varies based on the type of IUBT[8]. When using a condom balloon, the average volume required to achieve a hemostatic condition was 200–500 mL[6,12]. However, a study reported that nearly one-half (23/51) of respondents required more than 500 mL to manage bleeding[29]. Other studies also presented that infusion filling at or above 1000 mL resulted in the reversal of the uterine artery diastolic stream. It showed a significant correlation between incremental liquid volume and intraluminal pressure as well as uterine blood flow[30].

A condom is selected as IUBT because it has a low-pressure system containing a high-level volume and suits its inflated area within[31]. The balloons with a low intraluminal pressure–volume ratio are also indicated to fill the uterus more quickly and efficiently. In this study, the condom capacity of all brands and knot site types could reach up to 5000 mL without breaking. Its advantage is similar to the BT-Cath and ebb, the purposed-design IUBT, which can be inflated until the clinical maximum (5000 mL) without rupturing[9]. This volume is perhaps the highest to be allowed, particularly for condom balloons. However, it is necessary because the recent fluid restriction of balloon filling to 500 mL in some cases may confine the effectiveness of the balloon. Nevertheless, it has to notice the procedure. To prevent the risk of adverse effects such as uterine rupture or severe pain due to uncontrolled inflation, the following steps can be conducted: (1) gradually incrementing the liquid filling from 100 to 200 mL aliquots under ultrasound guidance[30], (2) using analgesic like pethidine if needed[8], and (3) strict

monitoring by healthcare providers for minimal uterine distension[8] and rigorously observing the patient's condition.

All condom types did not show leakage under either a varying volume or knot sites based on trials. The WHO Specification and Guidelines for Condom Procurement presupposes rigorous condom testing before being marketed, including conducting an airburst test, which determines whether the condom tends to break during use. The water or electronic test indicates any holes that could cause leakage. Several studies noted that the rate of condom failure differs from less than 1% to over 10%. The wide discrepancy in breakage rates was related to condom characteristics such as its shelf-life and user characteristics like less experienced[32]. Therefore, it is indispensable to check condom expiry dates and ensure that healthcare providers undergo condom balloon installation training.

When using condoms as IUBT, a few studies reported failure due to condom leaks. The balloon leak may be from the suturing needle during laparotomy after a cesarean section. The balloon being installed abdominally and then inflated following the uterine incision is sutured. As an alternative, it can be inserted through the vagina after closing the uterus[8]. Furthermore, this research certainly requires further clinical studies because it has not considered leaks due to balloon and uterus interactions, maternal movement effects, and other factors.

Catheter and IV Tubing

Catheter and IV tubing are a series part of a condom that can be used as IUBT. This study tested the device's flow velocity and length in different catheter sizes and when the catheter was removed from the set. Flow rate is notable because it affects balloon filling time leading to the achievement of homeostasis period. Blood supply to the uterine artery is approximately 500–600 mL per minute, and heavy bleeding causes blood loss > 150 mL/min[33]. In uterine atony requiring IUBT, it has taken much time after the first-line treatment using uterotonics failed[4,5], and it then needs a period to assemble component and install to uterus. Hence, accelerated actions such as draining fluids rapidly can help prevent further blood loss.

Several factors can influence the flow velocity, such as tube’s diameter and height of a gravity-fed[20]. However, this study has excluded the second factor by equalizing the height of the infusion pole from the top edge of the bed (130cm) to prevent fluid flow discrepancy due to differences in gravity-fed. Besides, it merely used one size of IV tubing. Therefore, the discussion focused on the type of catheter diameter size.

The condom combined with catheter no. 24F and no catheter had the fastest rate in draining liquid per 500 mL at 3.20 and 3.30 min, respectively, and the slowest was catheter no. 14F (5.40 min). Based on the statistical analysis, there was significant differentiation among seven types of catheters. However, the four bigger sizes (nos 18F, 20F, 22F, and 24F) and no catheter showed no significant discrepancy in streaming fluid. This result conforms to the Poiseuille's general law agreement; the larger and shorter tube, the greater flow[34]. Therefore, to optimize condom catheters as IUBT, using catheter no. 24F or removing catheters from the set can be a main option, followed by other big catheters (nos 18F, 20F, and 22F) if the prior choices are not possible. In limited areas, the recommended large catheter size (24F) is not always available in health facilities, so it can be an obstacle for using the device[35,17]. However, a study has shown that using a catheter do not significantly affect the application of the tools[17].

Nevertheless, deciding to remove the catheter as part of the condom must consider the device's length. One of the catheter's functions is to extend the IV tubing, which connects the infusion bottle and condom. Although applying the device is easier and quicker, the length should be fixed to the genital dimension and the distance between the infusion bottle and the external genital. Based on the measurement, the combined length of the condom catheter and infusion set was 190 cm, and if the catheter was removed, the set's length was merely 150 cm. Based on theory, the maximum average length of the female genital organ is 19 cm, including the uterus (7–9 cm)[36] and vagina (6–10cm)[26,37]. If the height of the infusion pole is 130 cm from the top of the edge delivery bed, the minimum required length of the device is 149 cm (130 cm plus 19 cm) (Fig. 3). So, removing a catheter can be sufficient even though it's too tight because, in the clinical setting, the distance between the infusion pole site and the patient's position should be reckoned. Ideally, the infusion pole is placed next to the patient's bed and side by side mother's pelvis. However, in a certain situation, such as in an emergency requiring much more equipment or health worker or in referring condition using an ambulance, the infusion pole may be situated in a different site so that it may need a more extended device.

Moreover, the mother's comfort in early mobilization should also be considered because a condom as IUBT can be in place for 24–48 h[8,12]. Other catheter functions can also shorten the device after hemorrhagic conditions have been established; the IV tubing can be removed, and the catheter opening can be tied to prevent fluids out. Alternatively, if it does not use a catheter, the IV line should be clamped and then neatly wound. Hence, it can allow mothers to move conveniently and safely.

Declarations

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Authors' contributions

Conceptual and experimental design: MM and MNR. *Data collection*: ZAN, MRC, and YTK. *Data analysis*: MM, MNR, and ZAN. *The first draft of the manuscript writing*: MM. *Paper reviewing and revising*: MNR, ZAN, MRC, and YTK. All authors read and approved the final version of the manuscript.

Competing of interest

The authors declare no competing interest

Availability of data and materials

All data generated or analyzed during this study are included in this published article.

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Tables

Due to technical limitations, table 1 and 2 are only available as a download in the Supplemental Files section.

Figures

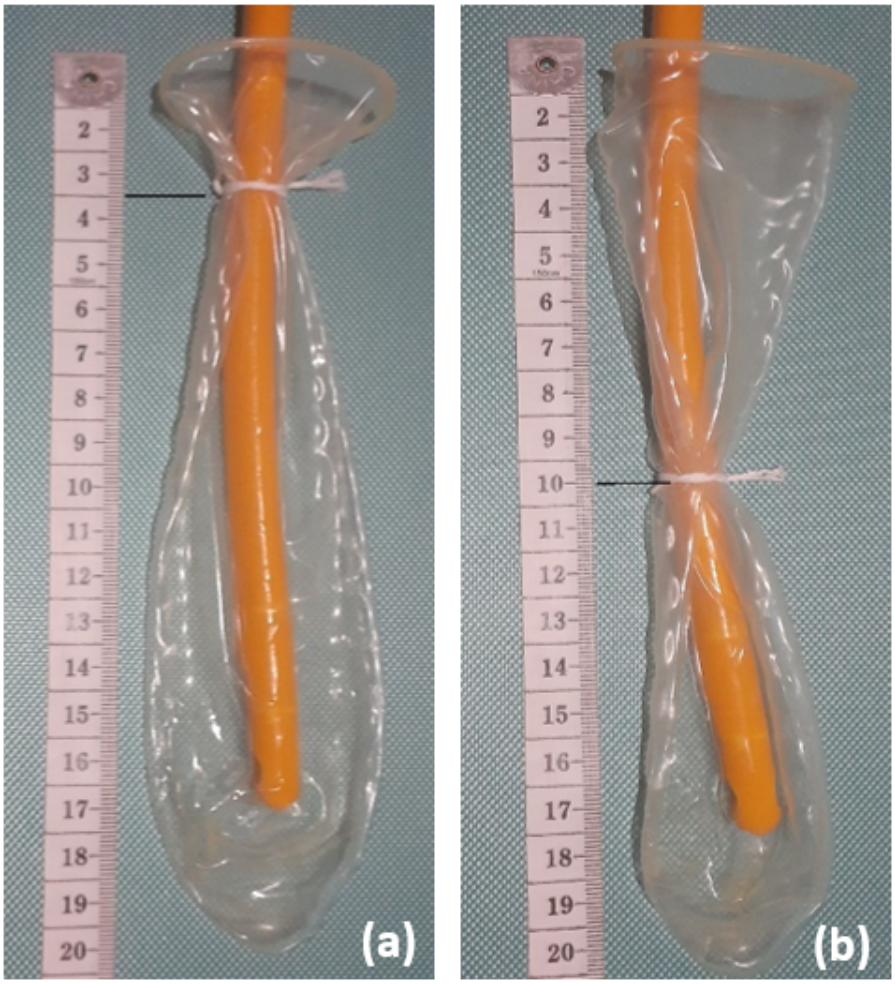

Figure 1

Type of the Knot Place: (a) The standard site (3cm from the tip); (b) The proposed site (in the middle of condom)

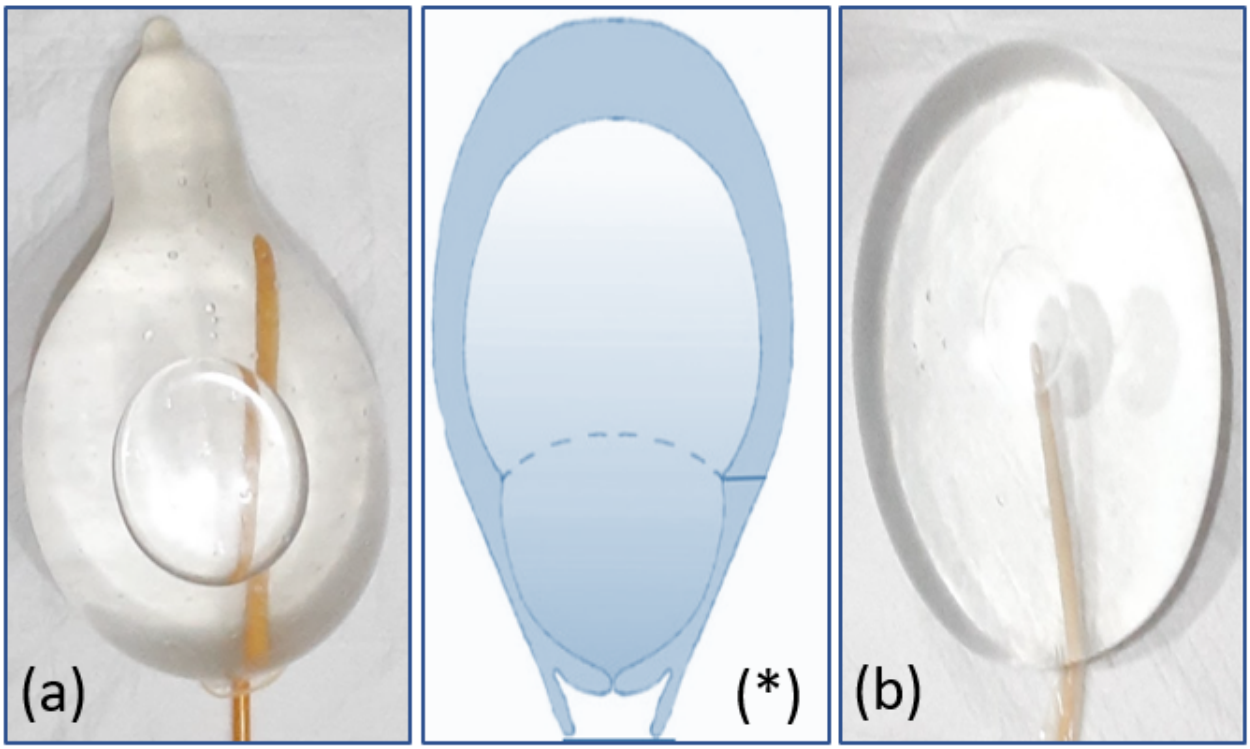

Figure 2

The illustration of shape condom difference based on two type knot sites in adjusted to uterus form: (*) The Uterus shape view (pear-shaped structure); (a) The standard knot site (inverted pear-shaped); (b) The proposed knot site (full round shape)

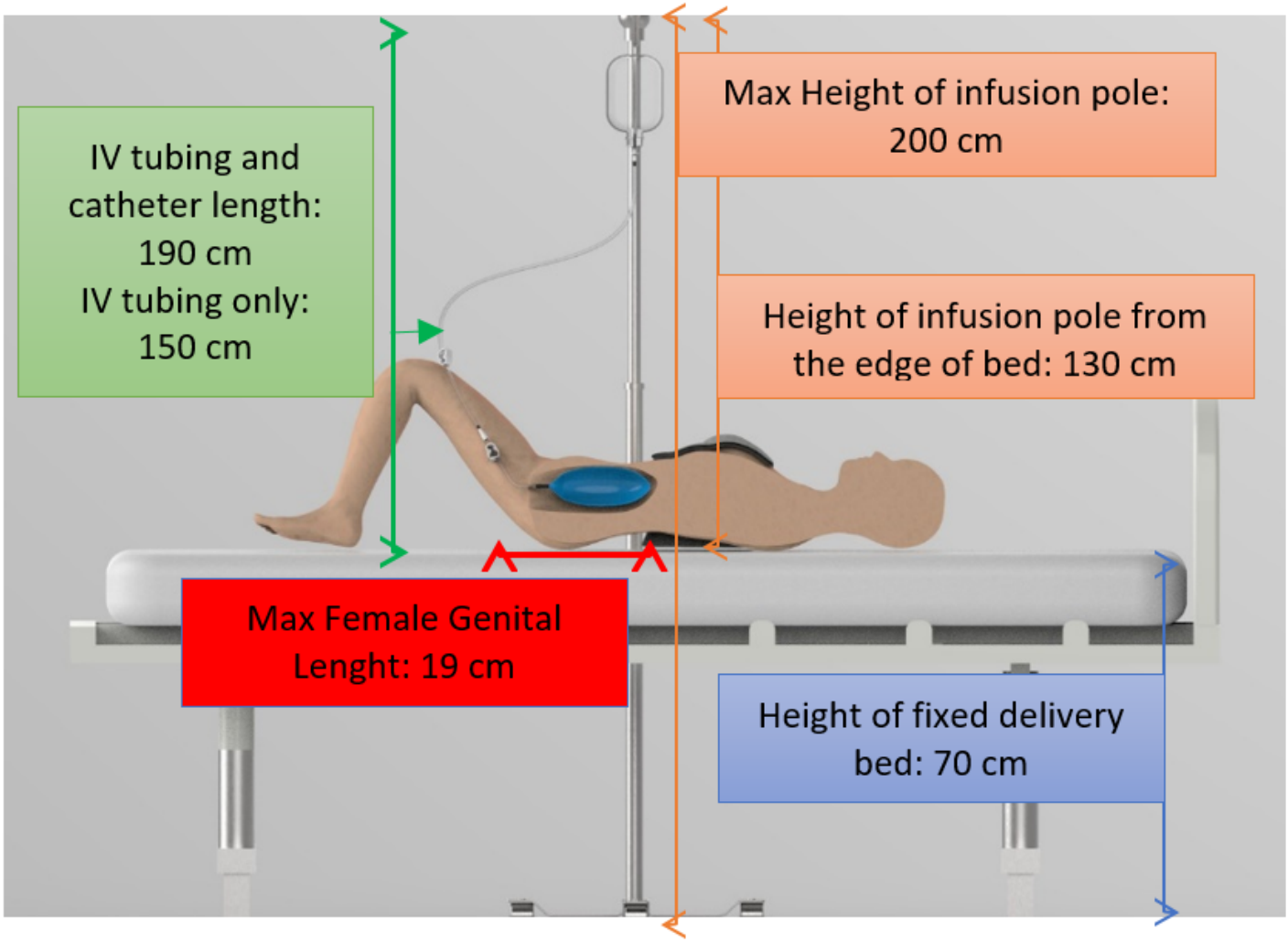

Figure 3

Illustration of the device length

Supplementary Files

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- Tables.docx