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The Value of Explicit Deliberative and ContextSpecified Ethics Analysis for Health Technology Assessment Evidence From a Novel Approach Piloted in South Africa

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Preference for uterine tamponade devices as a barrier to research: a provider survey

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OBJECTIVE: A recent review in the *American Journal of Obstetrics & Gynecology MFM*[1] reported reassuring safety and preliminary efficacy data for novel uterine suction tamponade devices, including "suction tube uterine tamponade,"[2] and emphasized that "well-designed" studies are essential. We conducted a randomized trial at 10 sites in South Africa comparing improvised low-cost suction tube uterine tamponade with balloon tamponade standard of care.[3] After steady recruitment over the first year, recruitment became very slow. Anecdotal reports from the sites suggested that providers at the participating hospitals had developed a preference for using suction tube uterine tamponade rather than randomizing participants. The current study objectively determined provider preferences for uterine tamponade devices.

STUDY DESIGN: We conducted an anonymous survey of providers at sites associated with the abovementioned study who had performed at least 1 suction and 1 balloon tamponade procedure. Article questionnaires were distributed to staff and returned in sealed envelopes. We asked participants to rank their preference for the method to use in the future (primary outcome) and to "please rank your experience" with tamponade devices they had used from 1 (very negative) to 10 (very positive) for the characteristics shown in the Table. The study protocol was approved by the University of Kwazulu-Natal Ethics Committee (reference number: BREC/00003677/2021).

RESULTS: Of 25 respondents, 2 were excluded as they had not performed any suction tube tamponade procedures. Respondents had more previous experience with balloon tamponade (the standard of care before the trial) than with suction tamponade. More respondents rated suction tamponade as their preferred method (78% vs 22%; $P<.001$). The respondents reported higher ratings for suction tamponade than balloon tamponade for comfort for the patient ($P<.05$), effectiveness ($P<.005$), speed of action ($P>.05$), and ease of monitoring ongoing blood loss ($P<.01$).

CONCLUSION: Our results suggest that providers who have used both methods generally prefer suction tamponade over

TABLE
Results of provider survey

Variable	Balloon tamponade												
	Elavi		Bakri		Condom		Glove		Total previous uses/ highest ranking outcomes (a)		Suction tube tamponade (b)		a vs b (*P* value)[a]
Baseline	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	
Previous use	18	2.5 (1–15)	9	7.0 (1–36)	9	3.0 (1–30)	6	2.5 (1–15)	19	8.0 (2–135)	19	3.0 (1–19)	<.005
Primary outcome	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)	
First preference[b]	21	1.5 (7)	12	2.5 (21)	11	0 (0)	7	1.0 (14)	23	5.0 (22)	23	18.0 (78)	<.001
Secondary	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	
Ease of insertion	20	7.0 (4–9)	11	8.0 (7–10)	10	3.5 (1–8)	6	5.5 (2–8)	22	7.0 (4–10)	22	8.5 (4–10)	.1
Patient comfort	21	6.0 (1–10)	12	7.5 (6–10)	11	6.0 (2–8)	7	7.0 (4–8)	23	7.0 (1–10)	23	8.0 (1–10)	<.05
Effectiveness	21	7.0 (2–10)	11	8.0 (7–10)	11	6.0 (2–8)	7	6.0 (3–8)	23	8.0 (2–10)	23	9.0 (6–10)	<.005
Speed of action	20	6.0 (1–8)	12	8.0 (6–10)	11	5.0 (1–8)	7	7.0 (5–9)	23	7.0 (1–10)	23	8.0 (4–10)	<.05
Monitoring ease	20	6.0 (1–10)	12	7.0 (6–10)	10	4.5 (1–7)	7	5.0 (4–7)	23	6.0 (1–10)	23	8.0 (4–10)	<.01

IQR, interquartile range.

[a] Wilcoxon signed-rank test or chi-square test (Mantel-Haenszel), Excel, and Epi Info software; [b] Where 2 first preferences were indicated, each was allocated 0.5.

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balloon tamponade. Provider perceptions do not necessarily represent the true superiority of 1 method over the other. Randomized trials are essential to determine the true effectiveness of treatments for postpartum hemorrhage (PPH). Provider preferences (loss of equipoise) may be a barrier to recruitment to individually randomized trials. Alternative methodology, such as cluster randomized trials, may be needed. Vacuum-induced uterine tamponade is intuitively attractive to practitioners, as promoting uterine contraction is aligned with physiological mechanisms of placental site hemostasis by myometrial vascular occlusion. The method has been reported as being in routine use with the improvised use of the Bakri balloon catheter as a suction catheter.[4] Intuitive preference for vacuum-induced tamponade may mitigate against objective research. Given the magnitude of the contribution of hemorrhage to maternal mortality, determining the optimal management of PPH unresponsive to first-line treatment with certainty through robust randomized trial methodology is a global priority.[5]

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