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Emergency physician utilization of transvaginal ultrasound after initiation of revised sterilization protocol^{*}



Bedside transvaginal ultrasound, performed by an Emergency Physician (EP), is an essential imaging modality in the emergency evaluation of a first trimester pregnant patient. This skill is essential in many clinical settings, where Imaging Sciences or Obstetrics departments are unavailable to perform these studies on an emergent basis. It is also designated by ACEP (American College of Emergency Physicians) to be a clinical competency required of EM (Emergency Medicine) physicians [1].

There is a widely accepted clinical workflow in the evaluation of the pregnant patient to confirm an intrauterine pregnancy: first, a transabdominal pelvic ultrasound (TAUS) is performed. If an intrauterine pregnancy (IUP) cannot be reliably identified, then the EM physician should move on to perform a transvaginal ultrasound. If an IUP cannot be identified transvaginally considering a quantitative beta-HCG at or above the discriminatory zone (usually 1500–2500 mIU/ml), OB is consulted. This will be referred to as the “rule-out ectopic pregnancy” process.

Achieving adequate disinfection of the transvaginal ultrasound probe is also an essential part of the Emergency Department workflow. Both the CDC and American Institute of Ultrasound in Medicine classify the transvaginal probe as “semi-critical”, meaning a device that comes in contact with mucous membranes [2,3]. The disinfection process recommended for semi-critical devices is high level disinfection (HLD), the “eradication of all organisms except bacterial spores” [2].

Previously, our institution had accomplished this disinfection process beginning with gross decontamination (removing the disposable cover and visible debris, wiping down with a clean cloth), then soaking in a 2% glutaraldehyde solution (Cidex®) for a period of 20 min.

Our emergency department recently enacted a new HLD policy on 7/1/2016 [4]. The revised protocol includes the aforementioned gross decontamination, then a disinfectant cleaning cloth, transportation of the probe in a biohazard bag to a processing area, then high level disinfection using Trophon®—an automated point-of-care machine utilizing hydrogen peroxide and a chemical indicator. After each processing cycle (7 min), the Trophon machine notifies the provider that the cycle is complete and whether or not it was successful. The results, along with the result of the chemical indicator (colorimetric pass/fail, interpretation based on a graphic displayed nearby), the patient’s medical record information sticker, the date and times of the cycle, and the cycle number, are then recorded by hand in an accompanying adjacent logbook.

^{*} This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

The goal of this new policy is to create a consistent disinfection process with compliant procedure documentation, to improve patient safety, and make a more effective workflow. However, the additional steps required may be perceived to impede workflow, leading ED providers to not perform the transvaginal scan, thus having a negative impact on physician and department workflow, overall cost, and patient safety. This study assessed the impact of the revised sterilization protocol on emergency physician-performed TVUS utilization rates pre- and post-protocol initiation. We also addressed the frequency of Obstetrics consultations pre- and post-protocol as some of these consultations can be obviated by successful identification of IUP by ED providers.

Study subjects were identified by manually reviewing our ED ultrasound imaging storage program, Sclmage. Subjects were all cared for at a single, large, urban and academic Emergency Department and tertiary referral center with an annual census of over 115,000. All pregnant patients who underwent pelvic ultrasounds in the ED (transvaginal or transabdominal) during the time period 6 months prior to the initiation of the policy (1/1/2016–6/30/16), and 6 months after the initiation of the policy (7/1/16–12/31/16) were included in the analysis. The patient’s MRN, age, date of service, provider (attending physician, resident physician, and/or advanced practice provider), pregnancy status, preceding transabdominal ultrasound (TAUS), whether or not an intrauterine pregnancy (IUP) was identified, whether the IUP was identified on TAUS or TVUS, OB/Gyn consultation, whether IUP was identified by OB/Gyn, and by what method (TAUS/TVUS) the IUP was identified were all recorded.

Each ultrasound study was manually reviewed by the research team (NG, TO, ME), who underwent specific study training in image interpretation and the study protocol. Charts were reviewed for demographics, lab values, documented ultrasound results, and presence or absence of OB consultation. We reviewed both the actual ultrasound clips within Sclmage, as well as the physician documentation within the electronic medical record (EMR). Any documented ultrasound interpretation was taken as final considering our intention to study the use of the sterilization procedure rather than image quality.

There were individual cases where it was determined that the provider misinterpreted the images (in most cases, an IUP was apparent on the available images, but subsequently documented as negative). For these cases, we recorded the documented interpretation used in the medical decision making, as this result drove subsequent additional imaging (for example, an unindicated TVUS) or an OB/Gyn consultation. Equivocal studies were reviewed during the Emergency Department’s weekly quality assurance process.

The study sample was characterized using descriptive statistics. To assess comparability of pre- and post-study samples, bivariate analyses were conducted. The proportion of subjects who underwent TAUS and TVUS as well as the proportion of OB consultations were quantified in the pre- and post-periods and compared using Chi-Square tests and Fisher’s Exact test as indicated. Given the exploratory nature of the study, a p -value < 0.05 was used to determine statistical significance and no adjustments were made for multiple comparisons. All data analysis was conducted in SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). 3.

3. Results

From January 2016 to December 2016, we reviewed charts to determine the frequency of pelvic ultrasound use, with attention to July 1st which marked the initiation of our revised sterilization protocol. During the pre-period 340 patients were evaluated for IUP, compared to 307 patients in the post-period. The ages of patients did not differ between time periods. After initiation of the revised protocol, the total number of TVUS decreased from 165 to 105 (Fig. 1). This represents an overall decrease in the rate of TVUS from 48% to 34%, a statistically significant decrease of 14% ($p < 0.001$).

Additionally, there was an increase in the overall number of OB consultations without an indicated TVUS (Fig. 2). This increase in OB

Number of TV US over 12-Month Period

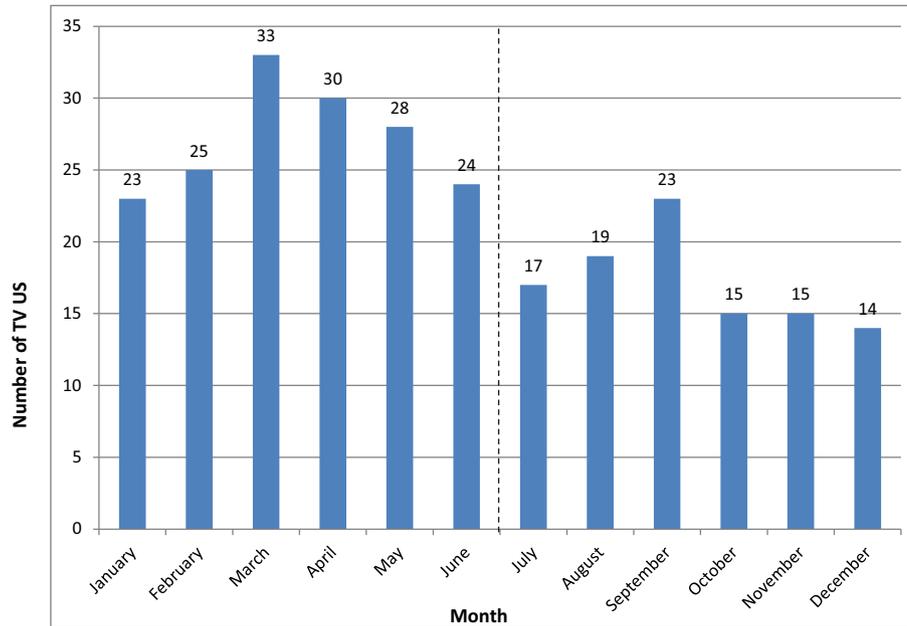


Fig. 1. Number of TV US over 12-month period.

consultation without indicated TVUS from 4 instances during the pre-protocol to 24 post-protocol supports the hypothesis that the revised sterilization protocol was associated with a general decrease in all TVUS and an increase in Ob/Gyn consults without TVUS.

There was also noted a concurrent significant decrease in the number of indicated TVUS after non-diagnostic transabdominal ultrasound from 81 to 55 (rate of 87% to 59%).

4. Discussion

Due to theoretical shortcomings of using a probe cover and using a low-level disinfection (LLD) strategy for probe hygiene, HLD is considered necessary for endocavitary ultrasound [6]. Probe covers have high rates of failure, LLD may leave residual viral DNA, and the probe handle is a potential source of residual infectious material [5]. Our study suggests that the processing of these probes via the Trophon HLD is associated with fewer exams being performed and more consultations. Implicitly, this is a comparison to the prior method of decontamination via Cidex immersion per AIUM and CDC guidelines. In our department, the prior process was clearly flawed, had inconsistent adherence, lacked the required ventilation hood and had poor associated adherence. The Trophon based HLD is faster and requires minor education but is plagued by an even greater burden with regards to documentation and workflow interruption.

The reasons for our findings are fairly easy to imagine: any new process has an associated learning curve and familiarity issues; ED workflow does not routinely allow for a 7 min process and its modest increase in associated documentation. Any new workflow has the potential to be a barrier to routine practice, and if the Trophon-based process is perceived as more cumbersome than the Cidex-based process it replaces, it may explain our findings. Another issue is what parts of the endocavitary probe need HLD. The probe shaft and tip are placed inside the vagina and thus require HLD, but the handle would be considered non-critical contact per the Spaulding Classification, casting doubt on whether or not the handle itself requires HLD [1,5]. Finally, despite residual contamination described in the aforementioned

publications, separating out what level of contamination leads to infection involves a good deal of speculation. Language around reasonable expectations of hygiene has yet to develop such that prudent lay people can judge their risk of exposure.

Our study raises the possibility that the safety initiative such as standardized HLD for endocavitary probes via Trophon has created an obstacle to standard care without clearly providing a benefit to patients. Our findings suggest that this may be an unintended deleterious consequence of a patient safety initiative. Appropriate use of older modalities may be effective from a patient safety standpoint but requires more human engineering solutions to prevent workflow interruptions and the expected downstream consequences. Furthermore, by discouraging the TVUS after a non-diagnostic TAUS the revised protocol has inadvertently increased the use of OB consultation the Emergency Department which almost certainly increased ED length-of-stay and decreases throughput.

Our study is limited by a number of factors. First, our data were obtained from a single institution and the generalizability of our findings may be limited due to large variations in clinical operations. Specifically, in our ED many patients undergo a medical screening exam at triage where a beta-hCG may have been ordered and already resulted by the time of physician involvement. Knowing the beta-hCG upfront could lead the ED provider to not follow the normal decision-making pathway. Secondly, patients are sometimes evaluated in beds located in hallways, which presents a barrier to performing TVUS in this setting. Examining bed placement by bed type (hallway vs. shared vs. private) may also have impacted TVUS use and OB consultation.

4.1. Conclusion

In conclusion, our study indicates that there may be an unintended consequence of the advent of a new HLD program for TVUS probe cleaning. We identified concerning trends that TVUS is used less since the Trophon HLD system was implemented in one Emergency Department. Whereas there are limitations to our study, further study is needed to confirm that HLD for TVUS is indeed good for patients from

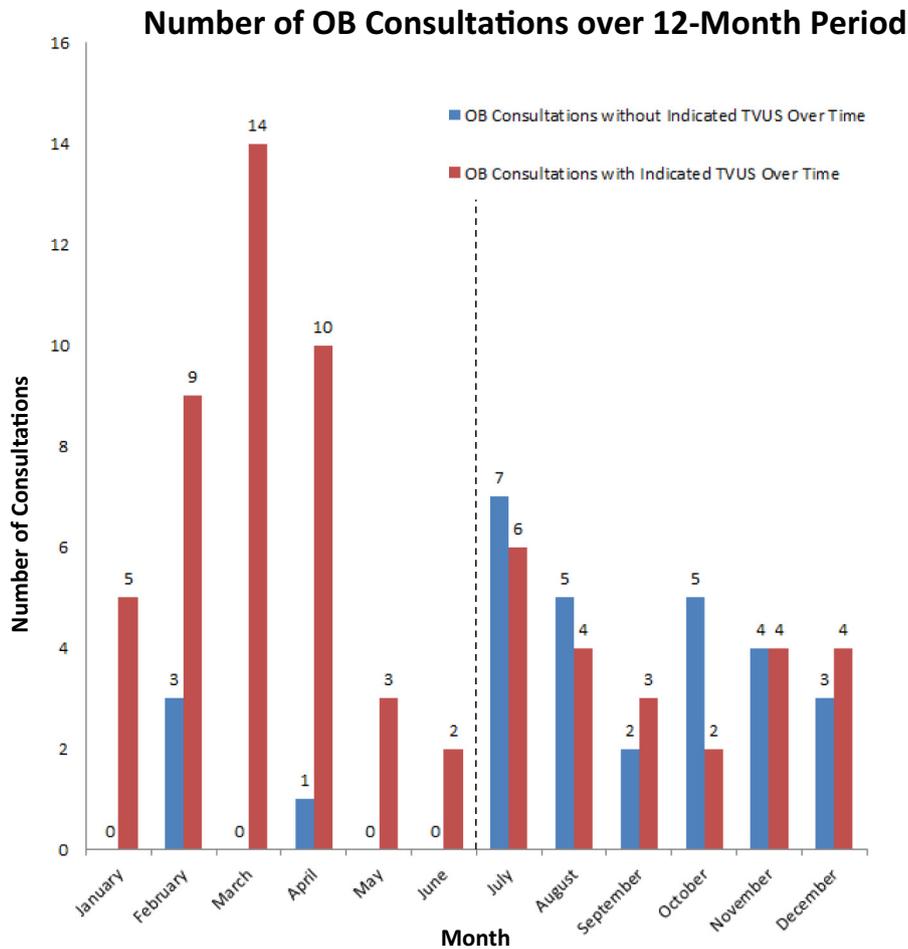


Fig. 2. Number of OB consultations over 12-month period.

a safety perspective. HLD is a more complex and expensive process than the process it replaces, these costs may be unintentionally suppressing standard Emergency care.

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28 August 2018

<https://doi.org/10.1016/j.ajem.2018.08.077>

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Which technique for resuscitation physicians should use? Preliminary data



Sir,

Sudden cardiac arrest is among the most serious health problems in both Europe and the United States [1,2]. The ability to perform cardiopulmonary resuscitation is among the basic skills that should be possessed by medical personnel, including physicians, nurses, and paramedics [3–5]. The current resuscitation guidelines emphasize minimizing interruptions in chest compressions as a key factor affecting resuscitation effectiveness and thus the return of spontaneous circulation. According to the current guidelines, high-quality chest compressions are characterized by an appropriate frequency of 100–120 compressions per minute (CPM), a corresponding compression depth of 50–60 mm, as well as complete chest relaxation after each compression [6]. Performing chest compressions in this way determines the most effective perfusion pressure and increases the chances for the return of spontaneous circulation [7,8]. According to many studies,