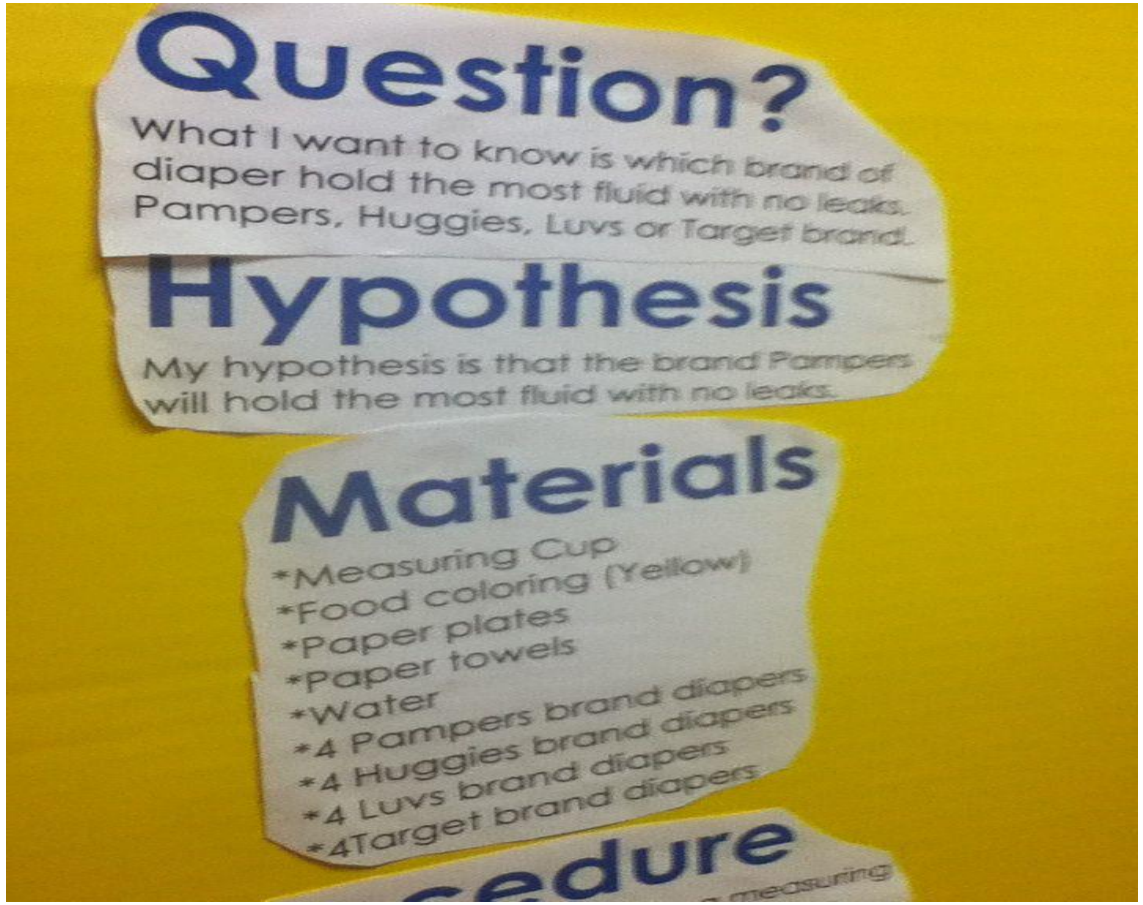
Akademik süreçte araştırma sorusu oluşturma ve doğru kaynağa ulaşım



Dr. Ramazan Güven

Başakşehir Çam ve Sakura Acil Tıp Kliniği

13.11.2020

Narrowing a topic

- İlgi çekici bir konu seçin
- Doğru referansları bulun
  - Başlangıç noktasını belirler
  - Konuyla ilgili doğru yolları bulmanıza yardımcı olur
  - Konu ile ilgili yazarları tanımanızı sağlayacaktır
  - Genel bir bilgi sağlar

Konudan araştırma sorusuna (From Topic to Research Question)

- Soruları keşfedin (Explore questions)
  - Genel konunuz hakkında açık uçlu “nasıl” ve “neden” soruları sorun.
  - Şimdi konununuzun ne olduğunu düşünün
  - Bu konu neden önemli
  - Başkaları için neden önemli
  - Seçtiğiniz sorular üzerinde düşünün. İlgi çekici bulduğunuz bir veya iki soruyu belirleyin ve bu sorular yeni araştırmalara olanak sağlıyor mu diye bakın

Figure 5. Bar chart (100%) showing the percentages of research types (experimental, quasiexperimental, and nonexperimental) by year: 1999–2015.

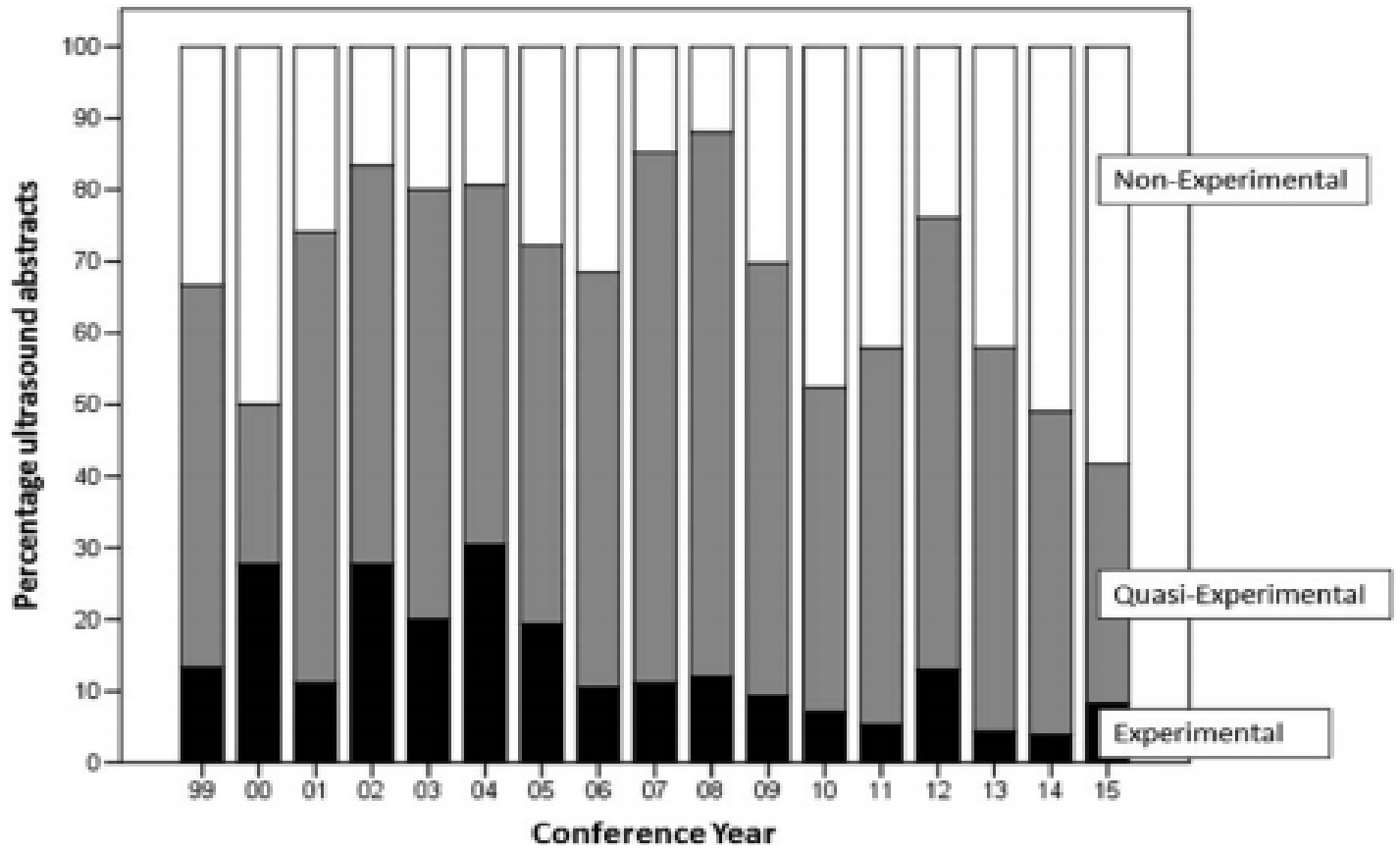
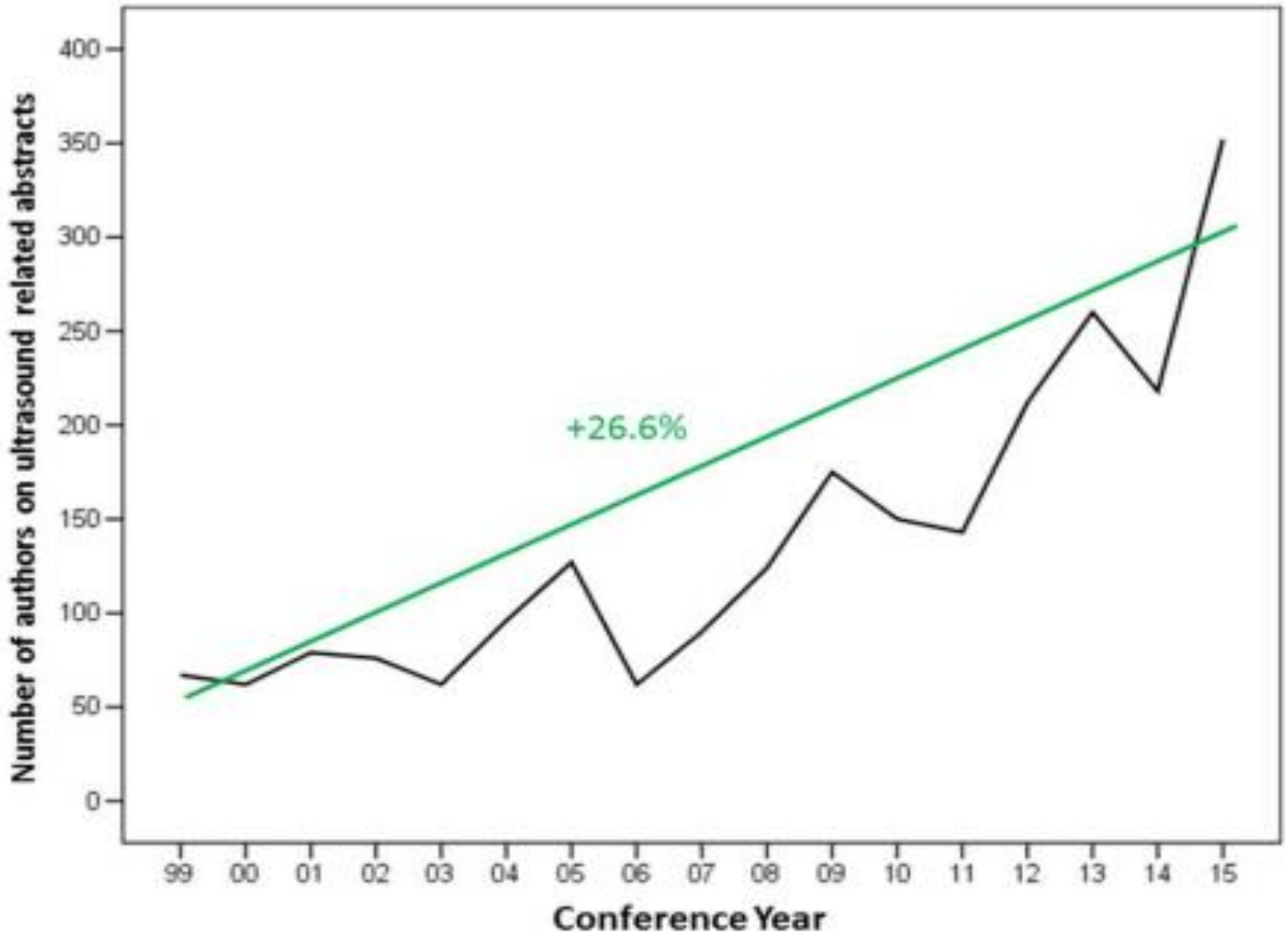


Figure 4. Trend line graph representing the number of authors involved with US abstracts accepted for the SAEM Annual Meeting with the rate of change by year: 1999–2015.



Kendine sor

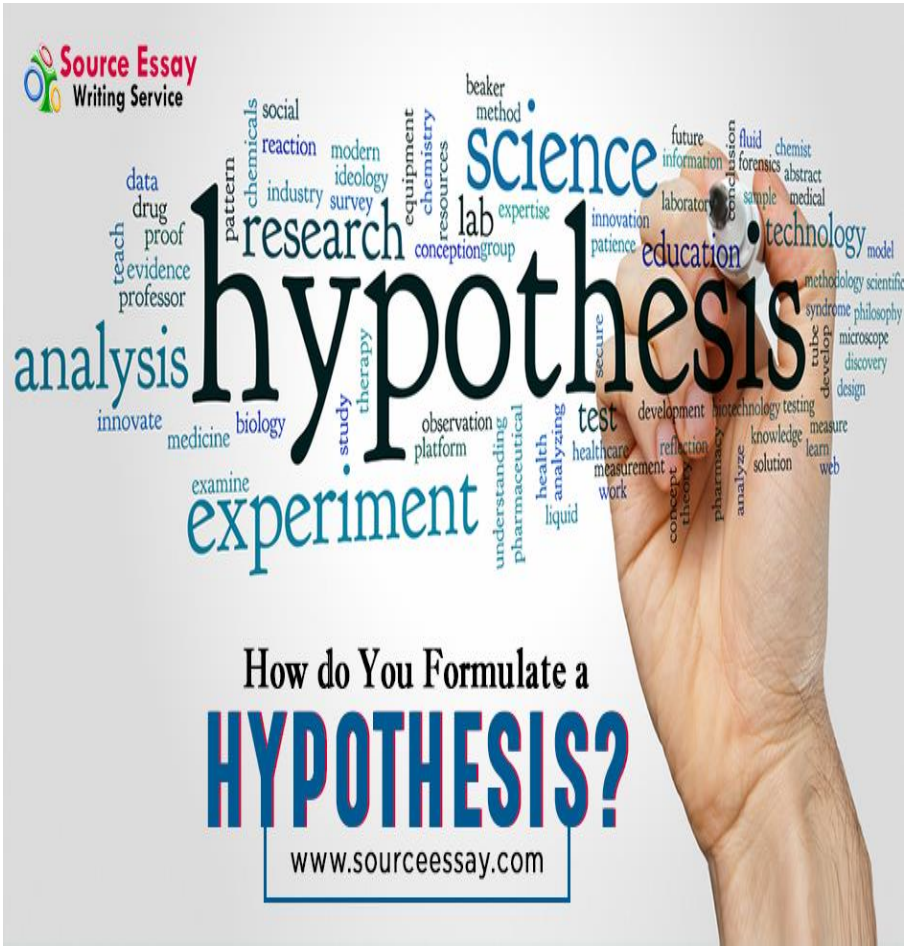
- Hangi alt konular ana konu ile ilgilidir
- Literatür taraması hangi yeni soruları getiriyor
- En ilgi çekici olanı hangisi
- Takımınızı seçin

Araştırma sorunuzu belirleyin ve değerlendirin

- Daha genel konunun hangi yönünü keşfedeceksiniz
- Araştırma sorunuz net mi?
- Araştırma sorunuz spesifik mi?
- Araştırma sorunuz kompleks mi? (Basit olmalı)

Hipotez

- Araştırma sorunuzun neyi cevapladığına bakın
- Eğer bir tartışmaya neden oluyorsa, savunulan düşünce
- Bu tartışma neden önemli
- Başkaları argümanınıza nasıl meydan okuyabilir? (How might others challenge your argument?)
- İddianızı desteklemek için ne tür kaynaklara ihtiyacınız olacak?



ACİL SERVİSTE SINIFLANDIRILMAMIŞ (UNDIFFERENTIATED) HİPOTANSİYON HASTALARINDA ODAKLANMIŞ ULTRASONOGRAFİ KLİNİK SONUCU (OUTCOME) İYİLEŞTİRİYOR MU? SHOC-ED ARAŞTIRMACILARINDAN RANDOMİZE KONTROLLÜ BİR ÇALIŞMA

October 2018 Volume 72, Issue 4, Pages 478–489

SHOC: SONOGRAPHY IN HYPOTENSION AND CARDIAC

Does Point-of-Care Ultrasonography Improve Clinical Outcomes in Emergency Department Patients With Undifferentiated Hypotension? An International Randomized Controlled Trial From the SHoC-ED Investigators

Paul R. Atkinson, MBBChBAO, MA, James Milne, MD, Laura Diegelmann, MD, Hein Lamprecht, MBChB, PhD, Melanie Stander, MBBCh, MMed, David Lussier, MD, Chau Pham, MD, MBA, Ryan Henneberry, MD, Jacqueline M. Fraser, RNBN, Michael K. Howlett, MD, MHSA, Jayanand Mekwan, MBBS, Brian Ramrattan, MBBS, Joanna Middleton, MD, Daniel J. van Hoving, MBChB, MMed, Mandy Peach, MD, Luke Taylor, MD, Tara Dahn, MD, Sean Hurley, MD, Kayla MacSween, Luke R. Richardson, MD, MPH, George Stoica, PhD, Samuel Hunter, Paul A. Olszynski, MD, MEd, David A. Lewis, MBBS

ABSTRACT

Study objective: Point-of-care ultrasonography protocols are commonly used in the initial management of patients with undifferentiated hypotension in the emergency department (ED). There is little published evidence for any mortality benefit. We compare the effect of a point-of-care ultrasonography protocol versus standard care without point-of-care ultrasonography for survival and clinical outcomes.

Methods: This international, multicenter, randomized controlled trial recruited from 6 centers in North America and South Africa and included selected hypotensive patients (systolic blood pressure <100 mm Hg or shock index >1) randomized to early point-of-care ultrasonography plus standard care versus standard care without point-of-care ultrasonography. Diagnoses were recorded at 0 and 60 minutes. The primary outcome measure was survival to 30 days or hospital discharge. Secondary outcome measures included initial treatment and investigations, admissions, and length of stay.

Results: Follow-up was completed for 270 of 273 patients. The most common diagnosis in more than half the patients was occult sepsis. We found no important differences between groups for the primary outcome of survival (point-of-care ultrasonography group 104 of 136 patients versus standard care 102 of 134 patients; difference 0.35%; 95% binomial confidence interval [CI] −10.2% to 11.0%), survival in North America (point-of-care ultrasonography group 76 of 89 patients versus standard care 72 of 88 patients; difference 3.6%; CI −8.1% to 15.3%), and survival in South Africa (point-of-care ultrasonography group 28 of 47 patients versus standard care 30 of 46 patients; difference 5.6%; CI −15.2% to 26.0%). There were no important differences in rates of computed tomography (CT) scanning, inotrope or intravenous fluid use, and ICU or total length of stay.

Conclusion: To our knowledge, this is the first randomized controlled trial to compare point-of-care ultrasonography to standard care without point-of-care ultrasonography in undifferentiated hypotensive ED patients. We did not find any benefits for survival, length of stay, rates of CT scanning, inotrope use, or fluid administration. The addition of a point-of-care ultrasonography protocol to standard care may not translate into a survival benefit in this group. [Ann Emerg Med. 2018;72:478-489.]

Please see page 479 for the Editor's Capsule Summary of this article.

ABSTRACT-STUDY OBJECTIVE

- H0 : Acil Serviste Sınıflandırılmamış (UNDIFFERENTIATED) Hipotansiyon Hastalarında sağkalım ve klinik outcome oranları açısındanPOCUS ile standart tedavi arasında FARK YOK.
- H1 : Acil Serviste Sınıflandırılmamış (UNDIFFERENTIATED) Hipotansiyon Hastalarında sağkalım ve klinik outcome oranları açısından POCUS ile standart tedavi arasında FARK VAR.

Study objective: Point-of-care ultrasonography protocols are commonly used in the initial management of patients with undifferentiated hypotension in the emergency department (ED). There is little published evidence for any mortality benefit. We compare the effect of a point-of-care ultrasonography protocol versus standard care without point-of-care ultrasonography for survival and clinical outcomes.

ABSTRACT-METHODS

- Uluslararası, çok merkezli (6 merkez kuzey Amerika-Güney Afrika), randomize kontrollü.
- **Evren:** Acil servise başvuran hipotansif hastalar
- **Örneklem:** Kuzey Amerika ve Güney Afrikadaki 6 merkezin acil servisine başvurup sistolik kan basıncı <100 mmHg veya şok indeksi>1 olan hastalar arasında çalışmanın dahil edilme kriterlerine uyan 400 hasta.
- **Primer outcome:** 30 günlük sağkalım veya taburculuk
- **Sekonder outcome:**
  - IV sıvı tedavi oranı,
  - İnotrop tedavi oranı,
  - CT scanning,
  - Yatış oranı (hospital and ICU)

Methods: This international, multicenter, randomized controlled trial recruited from 6 centers in North America and South Africa and included selected hypotensive patients (systolic blood pressure <100 mm Hg or shock index >1) randomized to early point-of-care ultrasonography plus standard care versus standard care without point-of-care ultrasonography. Diagnoses were recorded at 0 and 60 minutes. The primary outcome measure was survival to 30 days or hospital discharge. Secondary outcome measures included initial treatment and investigations, admissions, and length of stay.

Dahil edilme ve dışlama kriterleri

- **Dahil edilme kriterleri:** SKB<100, şok index>1 + SKB<120, yaş≥19
- **Dışlama Kriterleri:**
    - Gebelik
    - CPR gereksinimi olan durumlar veya ileri kardiyak yaşam desteği uygulanan hastalar
    - Son 24 saaate belirgin travması olanlar
    - EKG ile MI varlığı
    - Hipotansiyon veya şokun belirgin olduğu haller
    - Daha önce başvurduğu bir hastanede tanı alan hastalar (sevk/nakil)
    - Vagal hipotansiyon
    - hipotansiyonun fizyolojik olduğu haller (normal variant or other)

Bulgular

- Primer Outcome (30 günlük sağkalım veya taburculuk)
- POCUS + Standart Tedavi: 76.5%
- Standart Tedavi: 76.1%
- 95% CI: -10.2% – 11%
- Sekonder sonlanım: Fark yok

Results: Follow-up was completed for 270 of 273 patients. The most common diagnosis in more than half the patients was occult sepsis. We found no important differences between groups for the primary outcome of survival (point-of-care ultrasonography group 104 of 136 patients versus standard care 102 of 134 patients; difference 0.35%; 95% binomial confidence interval [CI] −10.2% to 11.0%), survival in North America (point-of-care ultrasonography group 76 of 89 patients versus standard care 72 of 88 patients; difference 3.6%; CI −8.1% to 15.3%), and survival in South Africa (point-of-care ultrasonography group 28 of 47 patients versus standard care 30 of 46 patients; difference 5.6%; CI −15.2% to 26.0%). There were no important differences in rates of computed tomography (CT) scanning, inotrope or intravenous fluid use, and ICU or total length of stay.

ABSTRACT-SONUÇ

- **Sonuç:** 270 hastanın istatistiksel analizi yapıldı. Buna göre;
  - H1 RED !

  - H0 : Acil Serviste Sınıflandırılmamış (UNDIFFERENTIATED) Hipotansiyon Hastalarında sağkalım ve klinik outcome oranları açısındanPOCUS ile standart tedavi arasında FARK YOK.

  - H1 : Acil Serviste Sınıflandırılmamış (UNDIFFERENTIATED) Hipotansiyon Hastalarında sağkalım ve klinik outcome oranları açısından POCUS ile standart tedavi arasında FARK VAR.

Conclusion: To our knowledge, this is the first randomized controlled trial to compare point-of-care ultrasonography to standard care without point-of-care ultrasonography in undifferentiated hypotensive ED patients. We did not find any benefits for survival, length of stay, rates of CT scanning, inotrope use, or fluid administration. The addition of a point-of-care ultrasonography protocol to standard care may not translate into a survival benefit in this group. [Ann Emerg Med. 2018;72:478-489.]

SORU:NASIL OLUR DA POCUS'UN SAĞKALIM ÜZERİNE ETKİSİ OLMAZ?

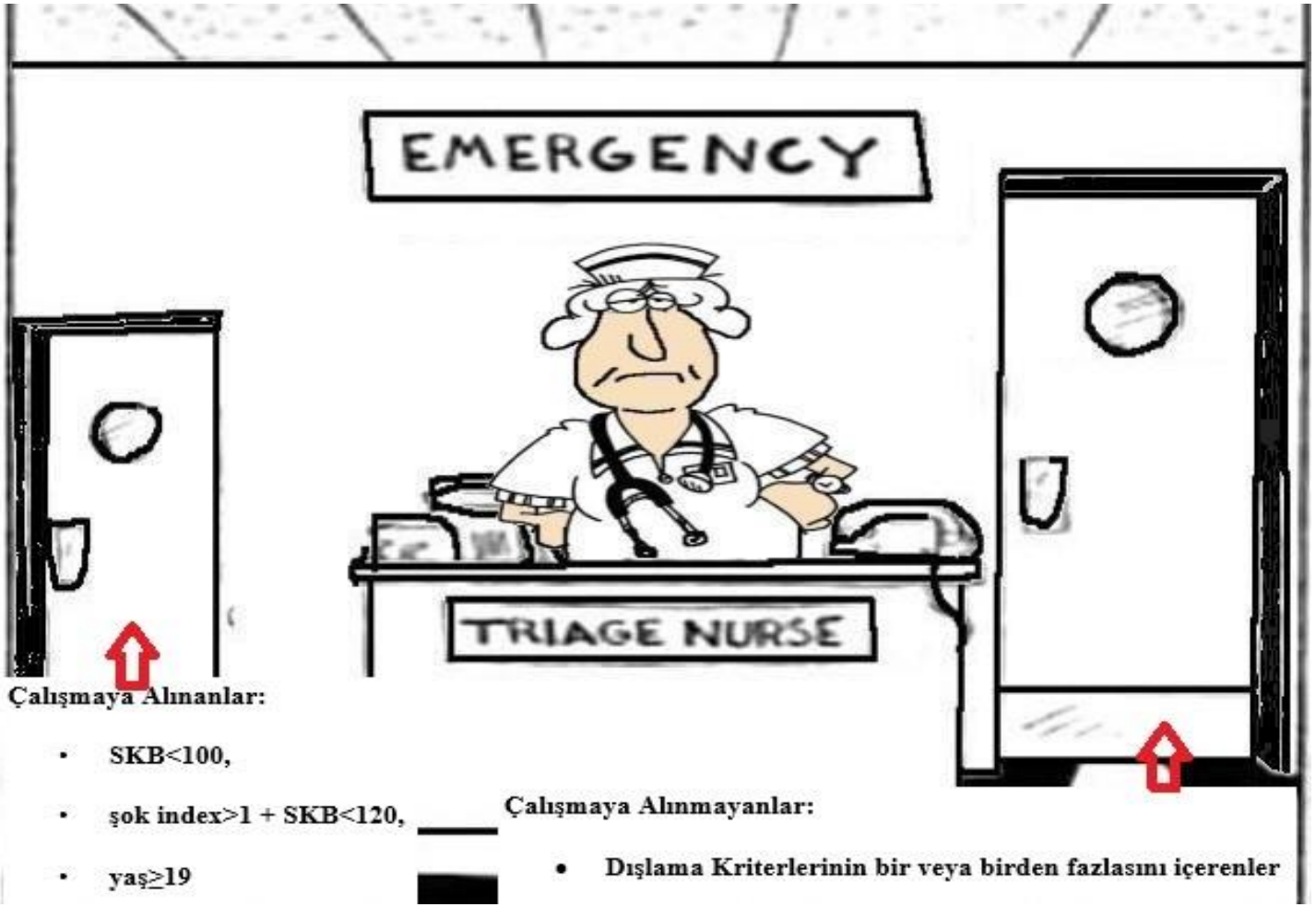
- HİPOTEZ Mİ YANLIŞ?
- BİAS MI VAR?
- KULLANILAN YÖNTEM/YÖNTEMLER Mİ YANLIŞ?
- SAMPLE SİZE MI YETERSİZ?
- POCUS ASLINDA YARARSIZ MI?

HİPOTEZ Mİ YANLIŞ?

- H1 : POCUS'un Acil Serviste Sınıflandırılmamış (UNDIFFERENTIATED) Hipotansiyon Hastalarında sağkalım ve klinik outcome üzerine etkisinin standart tedavi ile FARKI VAR.

- Bilinen kuramlarla çelişki içinde olmamalıdır
- Deney ve gözlemlere açık olmalı, test edilebilmelidir
- Mevcut zaman ve olanaklarla sınanabilecek biçimde sınırlı olmalıdır
- Hipotez cümleleri geniş zamanlı cümleler olmalıdır

Örneklem(Selection of Participants) ve Randomizasyon



Örneklem(Selection of Participants) ve Randomizasyon

- Convenience-sampling bloklama
- QuickCalcks-graphpad https://www.graphpad.com/quickcalcs/randomize1/
- Her merkez 50 kontrol+ 50 deney
- Zarflar: kapalı, opak, eşit büyüklükte, eşit ağırlıkta
- Çalışma formlarında her basamak ayrıntılı bir şekilde dolduruldu.
- Her iki grupta da 0. ve 60. dakikalarda olmak üzere başlangıç ve sekonder değerlendirmeler yapıldı.
- Deney grubunda sekonder değerlendirme USG den sonra yapıldı.
- Tanıların kategorize edilmesi ve nihai tanı USG bulgularına kör iki araştırmacı tarafından yapıldı. Disagreement varlığında 3. bir araştırmacının görüşüne de başvuruldu.

This study used randomized convenience-sampling blocks by site, and allocation concealment was performed at each site. QuickCalcs Random Numbers (version 2011; GraphPad Software, La Jolla, CA) was used to randomly assign either control (no point-of-care ultrasonography) or intervention (point-of-care ultrasonography protocol) documents to batches of 100 envelopes (50 of each group were assigned at each site), which were sealed, ensuring concealment of allocation. On completion of review of inclusion and exclusion criteria, and after obtaining consent, the physician retrieved a numbered sealed envelope that contained randomization details and the case report form. Randomization was also protected by the following measures: Researchers were provided with sequentially numbered prerandomized envelopes, which were opaque and matched for size and weight to ensure that it was impossible to discern between an intervention and control envelope. All locations had site-specific prefixes to the envelope numbers.

Case report forms included step-by-step instructions for performing, and fields for recording, ultrasonographic and clinical data. For patients randomized to the point-of-care ultrasonography group, physicians performed their normal initial clinical assessment and then completed the required point-of-care ultrasonography scans within the first 60 minutes of the patient visit, recording their data after each step. Patients in the control group received usual care without any point-of-care ultrasonography in the ED. Physicians recorded data after their initial clinical assessment without using point-of-care ultrasonography. In both groups, physicians performed a secondary clinical assessment and recorded their revised impressions at 60 minutes.

Categories of shock and diagnoses were established by independent chart review by 2 clinicians, blinded to the initial sonographer, point-of-care ultrasonography findings, arm of study, and initial and revised diagnoses. A third clinician was available to adjudicate for any disagreements.

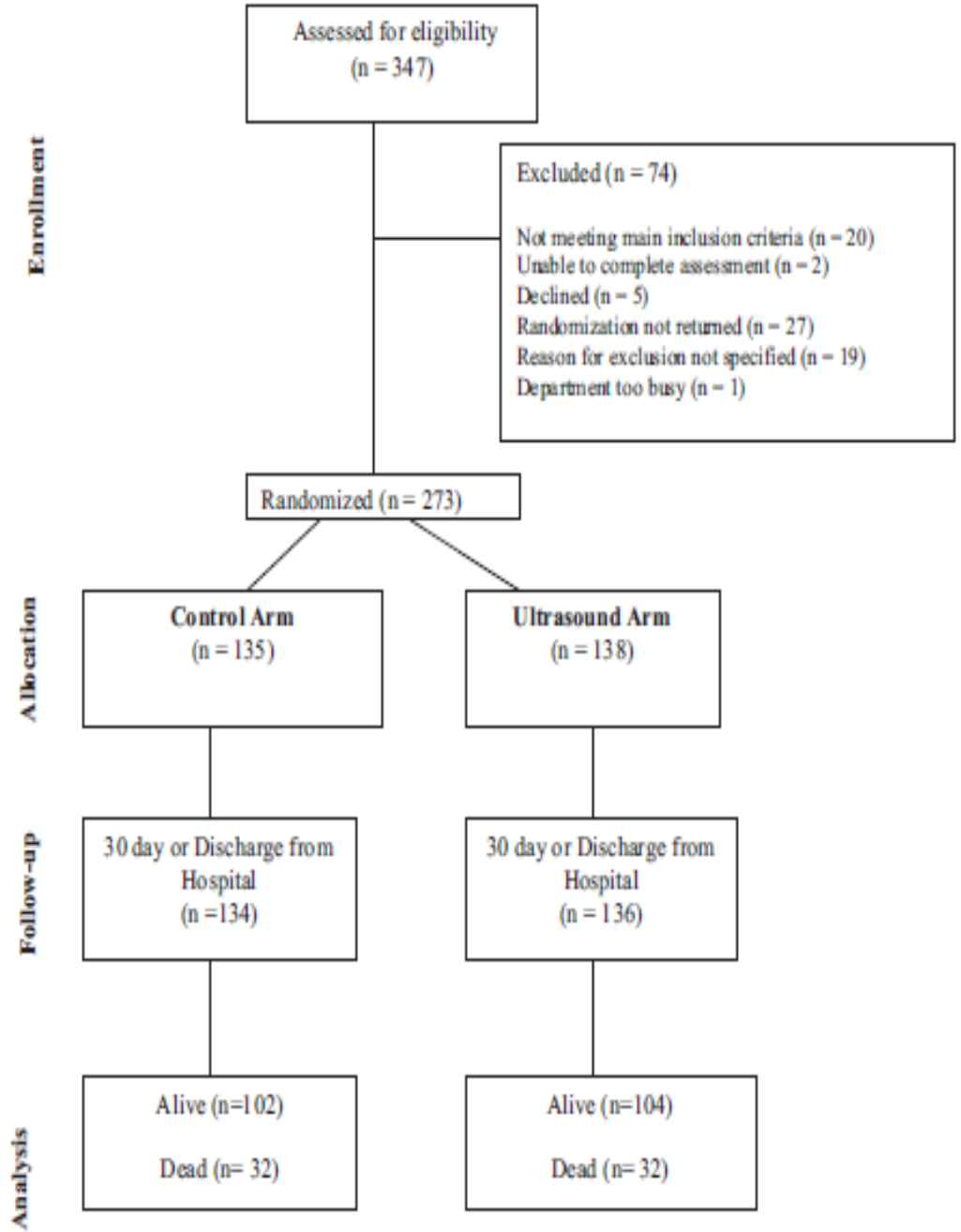
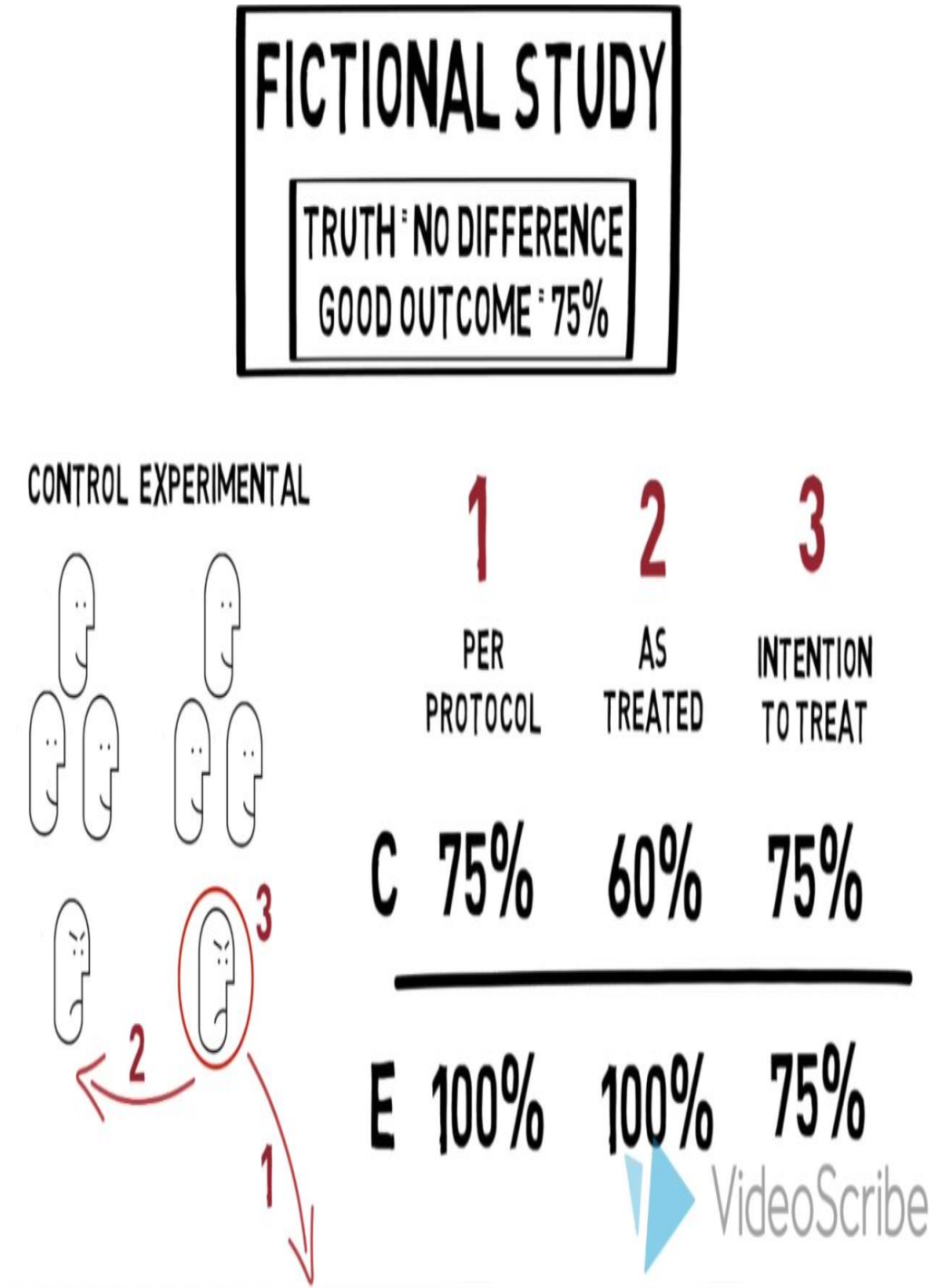


Figure 2. CONSORT flow diagram.



Per protocol

Table 3. Outcomes postintervention.

Group	PoCUS	Control	Difference in Proportion/Median, % (95% CI)
Total patients randomized, n	138	135	
Overall survival to 30 days/discharge, n*	104/136	102/134	0.35 (−10.2 to 11.0)
Survival North America, n	76/89	72/88	3.6 (−8.1 to 15.3)
Survival South Africa	28/47	30/46	5.6 (−15.2 to 26.0)
Intravenous fluid administered, median (IQR), mL	1,609 (1,412 to 1,816)	1,683 (1,456 to 1,924)	74 (−50.8 to 196.2)
Patients receiving inotropes, n	17/132	12/129	3.6 (−4.6 to 11.8)
CT scans performed, n	36/137	32/134	2.4 (−8.4 to 13.1)
Hospital admission, n	113/138	113/135	1.8 (−7.7 to 11.2)
Hospital length of stay, median (IQR), days	9.59 (8.15 to 10.86)	9.71 (7.84 to 12.26)	0.12 (−1.74 to 2.36)
ICU admissions, n	21/113	16/113	4.4 (−5.9 to 14.6)
ICU length of stay, median (IQR), days	7.16 (4.68 to 10.62)	5.14 (3.68 to 8.66)	2.018 (−0.85 to 4.63)
Lost to follow-up, n	2/138	1/135	0.06 (−2.9 to 4.4)

*Primary outcome.

LIMITATIONS

group (14.1%; binomial CI 8.3% to 22%), a difference of 4.4% (95% CI –6.1% to 14.8%).

The overall hospital length of stay was similar in each group, with a median of 9.59 days (IQR 8.15 to 10.86 days) in the point-of-care ultrasonography group compared with 9.71 days (IQR 7.84 to 12.26 days) in the control group, a difference of 0.12 days (IQR –1.74 to 2.36 days). The ICU length of stay was also similar in each group, with a median of 7.16 days (IQR 4.68 to 10.62 days) in the point-of-care ultrasonography group compared with 5.14 days (IQR 3.68 to 8.66 days) in the control group, a difference of 2.02 days (IQR –0.85 to 4.63 days).

Table 3 summarizes all primary and secondary outcomes.

LIMITATIONS

This remains a small study, with a significant number of exclusion criteria. We had initially planned to recruit 4000 patients; however, because of the slowing rate of recruitment, concerns about randomization to the control group from physicians, and the perceived futility of continuing at interim analysis as we approached two thirds of anticipated numbers of patients, the research ethics board advised stopping recruitment at the point reported. Despite the smaller final sample size, study power should not be a major concern. The actual observed difference in survival, the absolute risk reduction, is 0.35% (binomial 95% CI –10.2% to 11.0%). The associated number needed to benefit would be 285 (binomial 95% CI –10.2% to 9.5%, or number needed to benefit 9.5 to infinity, and number needed to harm 10.2 to infinity). As such, we cannot say with 95% certainty whether point-of-care ultrasonography is harmful, has no effect, or is beneficial compared with control, consistent with the research ethics board declaration of futility.

During the study design phase, because point-of-care ultrasonography had become more commonly used in EDs, there were initial ethical concerns about randomizing certain patients to the control group and restricting their access to point-of-care ultrasonography during their assessment. This led the study group to exclude pregnant patients with possible ruptured ectopic pregnancies and those with a high clinical suspicion for abdominal aortic aneurysm. In addition, patients with ST-segment elevation myocardial infarction on ECG and those with a "clear mechanism" of shock were also excluded. This resulted in randomizing only patients with truly undifferentiated or occult shock. The exclusion of these obvious suspected pathologies requiring critical therapeutic interventions may have detracted from any potential survival benefit with point-of-care ultrasonography use. The early adoption of point-of-care ultrasonography into emergency medicine before the completion of randomized controlled trials has limited the scope of this trial and any potential future comparative trials for point-of-care ultrasonography.

Making the diagnosis of occult sepsis (the ultimate diagnosis of more than half of the patients recruited) during initial resuscitation in the ED is difficult because such patients can have myriad point-of-care ultrasonography findings, depending on their premorbid status and their unique response to sepsis. The result is a spectrum of nonspecific point-of-care ultrasonography findings ranging from hyperdynamic to hypodynamic left ventricular function with variable inferior vena cava calibers, in addition to any preshock findings such as ascites or pleural effusions. In such settings, point-of-care ultrasonography may enable one to rule out critical diagnoses such as tamponade and abdominal aortic aneurysm, but may fall short of delivering the specific diagnosis.

In terms of sonographer skill levels, this study represents actual standards. All physicians performing point-of-care ultrasonography were trained, and each site had used local processes to confirm credentialing, qualifications, and skill level for ultrasonography. However, as demonstrated in Table E1 (available online at http://www.annemergmed.com), some physicians were at times not able to generate a complete point-of-care ultrasonography protocol with conclusive views. This could have negated any potential benefit in the point-of-care ultrasonography group, an issue that is difficult to resolve without all sites being fully staffed with ultrasonography experts, and one likely to reflect actual practice. Future work would benefit from storage of ultrasonography video clips for review and quality assurance. Having limited numbers of trained staff resulted in slower recruitment at some sites in particular.

Baseline characteristics were similar between the control and intervention groups for age and presenting vital signs, although there was significant heterogeneity between the North American and Southern African sites, with higher rates of sepsis in South Africa and more severe dehydration in North America, in addition to higher mortality overall at South African sites. Although this may limit the generalizability of the results, there was still no important outcome difference when point-of-care ultrasonography was compared with the control group at any site or when Southern African cohorts were compared with North American ones.

Finally, our point-of-care ultrasonography protocol did not include specific interrogation for anterior pneumothorax, interstitial syndrome, or consolidation, although it did not prohibit looking for these and did use base-of-lung ultrasonography to look for fluid. As point-of-care ultrasonography use develops, perhaps a future comparative study could include these parameters, as outlined in the recently published International Federation for Emergency Medicine–Sonography in Hypotension and Cardiac Arrest consensus statement.[28]

DISCUSSION

In this international randomized controlled trial, we found no important benefit with the addition of a point-of-care ultrasonography protocol for our primary outcome of survival to 30 days or hospital discharge for patients presenting to the ED in shock with undifferentiated hypotension. The findings are similar to those of a previous comparative trial of a point-of-care ultrasonography protocol versus standard care in trauma patients,[27] in which there was also no significant survival benefit for patients in the point-of-care ultrasonography group. Our study showed no important difference in the clinical secondary outcomes, with similar admission rates, need for ICU care and length of stay in both groups. There was also no important difference in the amount of intravenous fluids administered, inotrope use, or CT scans ordered.

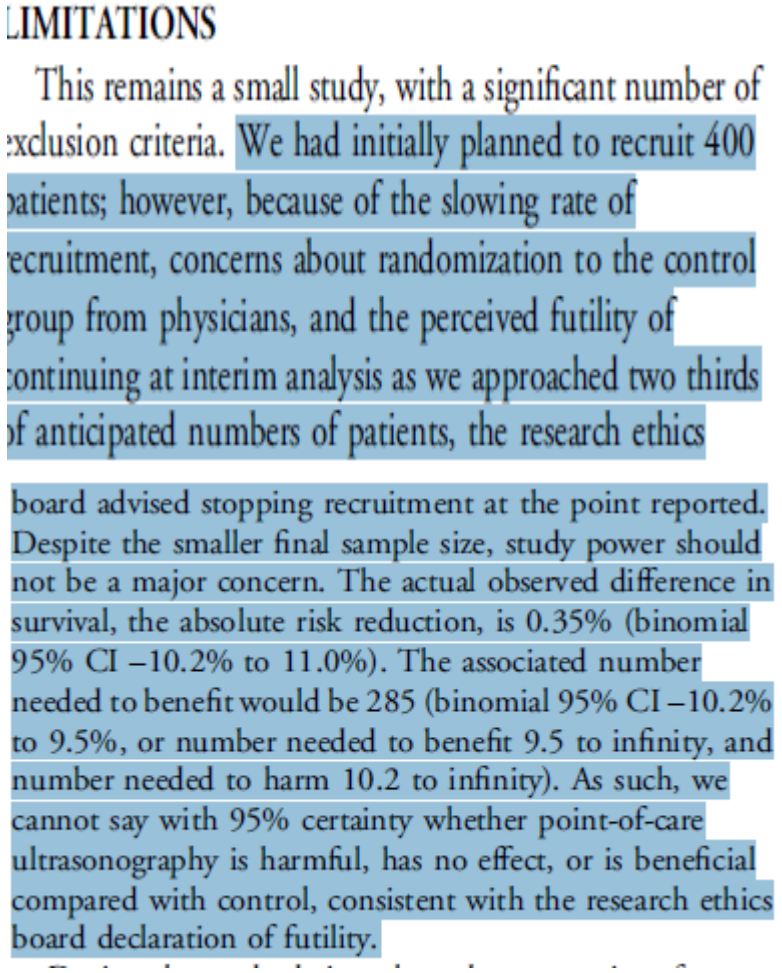
These results suggest that despite the additional information provided by the point-of-care ultrasonography protocol for patients in the intervention group, and without any point-of-care ultrasonography performed in the control group, all patients ultimately received similar care and had similar outcomes. Point-of-care ultrasonography is not a therapeutic intervention, and as such it may be unrealistic to expect the addition of this diagnostic tool to affect clinical outcomes such as length of stay or survival. There are several hypotheses that may explain this further.

First, it is possible that although point-of-care ultrasonography provides a high rate of abnormal findings, these pathologies are equally detectable by standard methods, without the use of point-of-care ultrasonography. As demonstrated by use of CT scanning in both groups, the comparison was not to discriminate between diagnostic point-of-care ultrasonography and no investigations, but rather between point-of-care ultrasonography and usual standard of care, which often included comprehensive laboratory and advanced imaging resources. However, there was no apparent advantage for patients in the point-of-care ultrasonography group in South Africa, where it could be argued that any benefit would be most apparent because of

LIMITATIONS

- Planlanan 400 hasta oldu ancak;
- Çalışmanın yavaş ilerlemesi, 2/3 hastaya ulaştıktan sonra yapılan ara analizde devam etmenin etik komitenin de tavsiyesiyle anlamsız olduğunu belirtmesi
- Etik kurulun bu tavsiyesi üzerine USG'nin zararlı, etksiz veya faydalı olduğu hakkında % 95 oranında bir kesinlik bulunmadığı
- Bu az sayıdaki hastada çalışmanın gücünün öncelikli hedef olmadığı

- NNT=285



LIMITATIONS

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SORU 1: NASIL OLUR DA POCUS'UN SAĞKALIM ÜZERİNE ETKİSİ OLMAZ?

- HİPOTEZ Mİ YANLIŞ?
- BİAS MI VAR?
- KULLANILAN YÖNTEM/YÖNTEMLER Mİ YANLIŞ?
- SAMPLE SİZE MI YETERSİZ?
- POCUS ASLINDA YARARSIZ MI?

- Yanlış hesap= mortalitede % 10 azalma
- Dışlama kriterleri geniş
- Dışlama kriterleri POCUS'dan asıl fayda görecek hastalar dışlanmış (STEMI, AAA, Travma)

SORU 2: O HALDE BU ÇALIŞMA NEDEN BASILDI?

IMAGING/ORIGINAL RESEARCH

Does Point-of-Care Ultrasonography Improve Clinical Outcomes in Emergency Department Patients With Undifferentiated Hypotension? An International Randomized Controlled Trial From the SHoC-ED Investigators

Paul R. Atkinson, MBBChBAO, MA*; James Milne, MD; Laura Diegelmann, MD; Hein Lamprecht, MBChB, PhD; Melanie Stander, MBBCh, MMed; David Lussier, MD; Chau Pham, MD, MBA; Ryan Henneberry, MD; Jacqueline M. Fraser, RNBN; Michael K. Howlett, MD, MHSA; Jayanand Mekwan, MBBS; Brian Ramrattan, MBBS; Joanna Middleton, MD; Daniel J. van Hoving, MBChB, MMed; Mandy Peach, MD; Luke Taylor, MD; Tara Dahn, MD; Sean Hurley, MD; Kayla MacSween; Luke R. Richardson, MD, MPH; George Stoica, PhD; Samuel Hunter; Paul A. Olszynski, MD, MEd; David A. Lewis, MBBS

*Corresponding Author. E-mail: paul.atkinson@dal.ca, Twitter: @eccucourse.

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An International Journal