studies due to pre-analytical and analytical factors. Harrison and Goodall emphasized categorically importance of that all blood samples should be collected, handled and processed in the same way so that the effect of pre-analytical variables in mean platelet volume (MPV) studies [2].

Secondly, although the platelet indices include platelet count, plateletcrit (PCT), MPV, and platelet distribution width may be routinely reported with complete blood count, their measurements have not standardized yet. Noris et al. reviewed the clinical importance of MPV measurement in recent years and they notified that because the wide variability of MPV as well as the very poor standardization of the methodologies used for MPV measurement, it has presently no role in making diagnosis and defining prognosis in any acquired illness in real life [3]. The MPV is dependent on time of analysis after sampling, method of analysis, anticoagulant used and specimen storage temperature [4]. The authors reported that blood platelets were measured usage with Sysmex XE 2100 hematology analyzer, but the measurement times after blood sampling were not standardized as specified in discussion. MPV increases progressively by exposure to EDTA. This increment in MPV occurs up to 30% within 5 min and then gains extra 10–15% over the subsequent 2 h [4]. The MPV measurements by the MPV measurement times varied up to 12.5% in a meta-analysis study and this difference was notified as 2–50% by the review of Jackson and Carter [4,5]. Because the measurement times after blood sampling were not standardized in this study, the accuracy of data was questionable.

PCT is the volume occupied by platelets in the blood as a percentage and calculated according to the formula; PCT = platelet count × MPV / 10,000 [6]. Therefore, the standardization problems related with MPV values affect the calculated PCT values. Thus, the accuracy of PCT data was questionable, too.

In conclusion, MPV and PCT values may not be associated with diagnosis and prognosis of gastrointestinal bleeding.

Declaration of interest statement

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Assessing the methodological quality of retrospective research protocols

Medical records are informal collections of impressions and observations that contain both objective and subjective information attained during the patient care process. They are not designed or created for research but frequently are used for this secondary purpose. While chart review studies tend to be inexpensive, relatively easily performed, and do not generally require specialized equipment, there are limitations to this type of study [1]. Information in medical charts is usually at least two steps removed from the patient with clinicians recording patient information, often with an intermediate transcription, followed by the chart abstractor recording data [2]. This can lead to recording errors, misinformation, and incomplete data. Understanding potential pitfalls in these studies allows the investigator to attempt to address them in the research design phase. Although there are no universally accepted criteria for a "well-conducted" chart review, there are recommended strategies to enhance the validity, reproducibility, and overall quality of data collected from clinical records [3,4]. The aim of our study is to review research proposals submitted to the Institutional Review Board (IRB) at one academic medical center to 1) determine the proportion of research protocols that use data exclusively from chart reviews; and 2) assess and quantify the quality of these protocols using published methodologic criteria.

We conducted a retrospective cross-sectional analysis using research proposals submitted to the IRB at one academic-affiliated medical center during a one-year study period. Inclusion criteria included any original research proposals that relied solely on data from medical records to answer the questions posed by the study. Exclusion criteria included research proposals relying on death certificates, coroners' reports, or other public records, and all studies based on animal or laboratory investigations. Additional exclusion criteria included retrospective studies based on aggregate patient data and computerized databases, case reports and case series, systematic reviews, studies withdrawn by investigator, and those studies categorized as not human subjects research (NHSR).

Experienced IRB analysts evaluated the quality of protocols using a checklist of methodological criteria adapted from the published literature in collaboration from the Department of Epidemiology at Michigan State University [3-5]. For each criterion, a rating of "Yes" or "No" was assigned. Credit was given if the investigators mentioned the methodologic standard, whether or not details were provided. In order to ensure the accuracy of data abstraction, all of the investigators assessed several mock research proposals to evaluate the consistency of coding and to clarify the coding system. One investigator met frequently with abstractors to resolve questions and ensure consistency of abstraction and coding. Any proposals that were questionable were evaluated by all investigators and discussed to reach consensus and assign a code. A blinded critical review of a random sample of 10% of the charts was done to determine interrater reliability. The interrater agreement for this sample of charts was determined using kappa statistics. Descriptive statistics (mean, SD) and frequency tables were used to describe the key quantitative and qualitative variables.

During the study period, 265 studies were submitted to the IRB; 100 studies were excluded from analysis because they were categorized as NHSR (60%), exempt (19%), withdrawn by investigator (18%), or were evaluated primarily by another IRB (3%). A total of 165 protocols were included in our analysis. This represented 76% of all the eligible protocols submitted in 2015. These retrospective protocols represented 28 medical specialties, including orthopedics (15%), pediatrics (11%), surgery (10%), pharmacy (9%), cardiovascular (8%), and emergency medicine (6%). Faculty physicians were generally the principal investigators (PI) (72%), followed by residents (15%), pharmacy staff (8%), nursing staff (2%) and medical students (2%). There was wide variability (3.6%

to 95.2%) in the adherence to each of the 17 methodologic standards (Table 1). The highest adherence was found for studies containing a clear description of study objective or hypothesis (95%) and protection of confidentiality (88%). The lowest adherence to methodologic standards was found for abstractor blinding to hypothesis (3%), plan for missing data (4%), and testing of interrater reliability (7%). Over half of the protocols (56.1%) were sent back to PIs for revisions prior to final approval. Interrater reliability was calculated across the 17 methodologic criteria; the consistency of the data recording was excellent, with a median kappa statistic of 0.89.

Table 1
Retrospective protocols that adhered to methodologic standards.

	Proportion	95% CI
Clear hypothesis or aim	95.2%	91.9–98.5
Confidentiality measures	87.9%	82.9–92.9
Intervention described	87.7%	81.5–94.0
Case selection criteria	79.9%	73.8–86.0
Abstraction forms included	78.2%	71.9–84.5
Diagnostic methods explained	66.1%	57.9–74.3
Comparison group defined	60.0%	48.5–71.5
Medical database identified	54.0%	46.4–61.7
Definition of study variables	49.7%	42.1–57.3
Participating institutions listed	49.4%	41.6–57.2
Sampling method described	45.6%	37.8–53.4
Sample size calculated	35.6%	28.2–43.0
Training of abstractors described	13.4%	8.1–18.7
Monitoring of abstractor performance	8.4%	4.0–12.8
Interrater reliability tested	7.2%	3.1–11.3
Missing-data plan	3.7%	0.8–6.6
Abstractors blind to hypothesis	2.6%	0.1–5.1

Retrospective research studies continue to comprise a significant proportion of original research in academic medical centers. If the criteria used in this study are reasonable indicators of scientific validity, our findings suggest that greater effort should be made to improve the methodologic quality of retrospective protocols. Adherence was below 50% for 9 of the 17 criteria assessed (Table 1). These findings are similar to reports assessing the methodologic quality of medical record review studies published in emergency medicine journals [4-6]. Education for researchers to improve protocol writing and adherence to agreed-upon methodologies to promote accurate, thorough and useful research is of utmost importance. Investigators must recognize the limitations and challenges of the medical record and take steps to add rigor to the data collection process.

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Reply to the Letter titled "Platelet indices may not be associated with diagnosis and prognosis of gastrointestinal bleeding"

I've read the letter titled "Platelet indices may not be associated with diagnosis and prognosis of gastrointestinal bleeding", which was sent by an esteemed reader, with great interest.

The reader points out that the preanalytical and analytical factors are of great importance for concluding the hemogram measurements normal. It is expressed that complete blood counts should be carried out by taking this factors into consideration in the abnormal hemogram results. As expressed by our reader, many factors play a role in the healthy measurement of complete blood count. Therefore, in patient selection, complete blood counts are repeated for a second time for the purpose of confirming the results in those patients with abnormal platelet count, and the patients demonstrating similar results are included in the study. The patients who have a significant difference between the first and second measurements are not included in the study. We are sorry that we did not include this detail in the method part of the study.

The second criticism of the reader is that mean platelet volume (MPV) is not suitable for use to determine a clinical situation since its standardization cannot be performed. This parameter is studied using the same brand devices and same parameters in our hospital. And platecrit calculated with MPV levels are measured as explained above. Here, we express that platelet indices measured with the same method and standard may be related to gastrointestinal bleeding diagnosis and prognosis. That is, there is a probability here. Taking into consideration the speculations made towards this result in the discussion of our study, changes may occur in the platelet indices in the event of gastrointestinal bleeding physiopathologically.

Indeed, there are tens of studies in the literature, reporting the relation of platelet indices with clinical situations [1-7].

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The authors declare that they have no conflict of interest.

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