Practice Management Guidelines For Trauma Patients: Where's The Evidence?

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Citation

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Abstract

Objective: Evidence-based practice management guidelines (PMGs) have been developed by various medical specialties in order to reduce variation in practice and promote resource-effective management. The purpose of this study was to assess the type of literature available for development of PMGs for trauma.
Methods: A Medline search was performed from 1/1/95 TO 7/31/98 to develop a reference list of clinical trauma citations from 10 peer-reviewed journals. Clinical abstracts presented at national meetings from 3 trauma organizations (EAST, WTA, AAST) during the same period were also identified. Articles and presented abstracts were classified as class I (prospective, randomized), class II (prospective, non-randomized), class III (retrospective). An additional category (class IV) was designated specifically for case reports.
Results: 1477 articles and 498 abstracts were reviewed. Articles were classified as 60 class I (4.1%), 262 class II (17.7%), 649 class III (43.9%), and 506 class IV (34.3%). The Journal of Trauma contained the greatest number of class I (32), II (172), and III (472) articles related to trauma. Surgery (29.2%) and Annals of Surgery (21.4%) contained the greatest proportion of class I articles among trauma articles published in their respective journals. Presented abstracts were classified as 36 class I (7.2%), 197 class II (39.6%), 262 class III (52.6%) and 3 class IV (0.6%).
Conclusion: There is a deficiency of both published and presented class I clinical research in trauma. Retrospective reviews and case reports dominate clinical trauma research. The lack of prospective, randomized data must be considered in the validation of current PMGs, the development of new PMGs and the evolution of clinical practice.

INTRODUCTION

The forces of managed care in the healthcare marketplace require the contemporary physician to be more resource-efficient. Healthcare providers are called upon to minimize the cost of services while ensuring the best possible patient care. The practitioner must promote the interest of the patient in the context of financial restrictions imposed by managed care organizations. Recently, practice management guidelines (PMGs) have been advanced by various medical and surgical specialties as one strategy to maintain quality patient care while optimizing resource utilization. Designed to maintain a safe balance between care and costs, PMGs are intended to provide consistent, efficient and cost-effective treatment while reducing variance in practice patterns and inappropriate resource utilization.[1]

Patient management guidelines are evidence-based, developed from the best quality literature available in conjunction with multidisciplinary opinion from experts in a respective field. Graded recommendations are subsequently formulated based on the availability and quality of the literature reviewed. Level I recommendations are derived from prospective, randomized trials (class I). Prospective, non-randomized studies (class II) are used to develop level II recommendations. Finally, level III recommendations are based on retrospective studies (class III), small series and individual case studies.[2,3,4]

National organizations and individual institutions have developed and implemented PMGs. Despite their intuitive benefits, PMGs have not been widely embraced by the trauma community at large. One potential explanation for the lack of universal acceptance may be the paucity of quality data upon which to base guidelines specific to trauma care.2 In order to clearly establish this impression, this study

was proposed to examine the recent trauma literature with regard to its suitability for the development of PMGs.

METHODS

Ten peer reviewed surgical and emergency medical journals were identified as sources from which literature specific to the field of Traumatology would be reviewed [Table 1]. These journals were selected specifically based on their popularity within their respective specialty or subspecialty and their tendency to publish studies pertinent to trauma.

Figure 1

Table 1: Selected Journals

TITLE	ABBREVIATION
Annals of Emergency Medicine	Ann Emerg Med
Annals of Surgery	Ann Surg
Archives of Surgery	Arch Surg
Journal of Academic Emergency Medicine	J Acad Emerg Med
Journal of the American College of Surgeons	JACS
Journal of Neurosurgery	J Neurosurg
Journal of Pediatric Surgery	J Ped Surg
Journal of Trauma	J Trauma
Surgery	Surg
World Journal of Surgery	World J Surg

A Medline search was performed using the subject headings "trauma" and "wounds and injury" for the period from January 1, 1995 through July 31, 1998. The search was limited to human studies published in English. A list was then compiled of all citations derived from the search available from each of the selected journals. Individual articles were screened to determine whether they were, in fact, related to trauma (i.e. trauma article). An article was defined as a trauma article if it discussed injury of such severity that life or limb is threatened.[5] Studies primarily related to iatrogenic injuries, review articles and editorials were excluded. Trauma systems articles were included only if data was collected and used to formulate a conclusion. References from the Journal of Trauma were exempt from this screening process. All published clinical citations were considered to be trauma articles. The final reference list of trauma articles comprises the study material.

Abstracts presented at the Eastern Association for the Surgery of Trauma (EAST), the Western Trauma Association (WTA) and the American Association for the Surgery of Trauma (AAST) were then collected from annual meetings held between January 1, 1995 and July 31, 1998. Basic science abstracts were excluded from further review.

Articles from the final reference list and the list of presented abstracts were distributed among the authors and reviewed individually. Each article or abstract was classified according to the system for assessment of scientific evidence recommended by EAST as class I, II or III.[2,3] For purposes of this study, a fourth class was defined (class IV) to include only case reports [Table 2]. Other classifications systems define case reports as class III.

Figure 2

Table 2: Classification of Scientific Evidence [2,3]

CLASS	DESCRIPTION
Class I	prospective randomized controlled trials
Class II	retrospective analysis of prospectively collected data
Class III	studies based on retrospectively collected data, including clinical series, database and registry reviews, and expert opinion
Class IV†	case reports

†Classification developed by authors.

This research did not involve human subjects or therapeutic interventions. Based on the study design, the research was exempt from IRB approval.

RESULTS

Medline identified 2612 citations using the subject headings "trauma" and "wounds and injury" for the designated time period (January 1, 1995 – July 31, 1998). Following screening, exclusions as defined and including all citations from Journal of Trauma, a final reference list of 1477 trauma articles was compiled for review [Table 3].

Figure 3

Table 3: Selected citations

JOURNAL	MEDLINE CITATIONS	TRAUMA CITATIONS
Ann Emerg Med	208	53
Ann Surg	55	28
Arch Surg	105	53
J Acad Emerg Med	137	32
JACS	55	26
J Neurosurg	193	62
J Ped Surg	144	67
J Trauma	1582	1115
Surg	70	24
World J Surg	63	17
TOTAL	2612	1477

Results of the review are summarized in Table 4. There was 60 (4.1%) class I and 262 (17.7%) class II articles. The majority of articles were class III (43.9%) and class IV (34.3%). When case reports were excluded (i.e. class IV) from review, the reference list included 971 articles. Within this subgroup, 6.2% of the articles were class I, 27.0% class II and 66.8% class III. Of the journals reviewed, Surgery and Annals of Surgery contained the greatest relative proportion of class I articles. 29.2% of articles reviewed from Surgery, and 21.4% of articles reviewed from Annals of Surgery were class I. Journals with the fewest class I studies were Annals of Emergency Medicine (0%) and Journal of Neurosurgery (1.6%). Articles from the Journal of Trauma were classified as follows: 32 (2.9%) class I; 172 (15.4%) class II; 472

(42.3%) class III; 439 (39.4%) class IV 81.7%.

Figure 4

Table 4: Classification of trauma citations

JOURNAL	Class I	Class II	Class III	Class IV	TOTAL
Ann Emerg Med	0	10	29	14	53
Ann Surg	6	8	14	0	28
Arch Surg	2	13	36	2	53
J Acad Emerg Med	5	6	18	3	32
JACS	3	8	15	0	26
J Neurosurg	1	25	15	21	62
J Ped Surg	2	6	36	23	67
J Trauma	32	172	472	439	1115
Surg	7	7	8	2	24
World J Surg	2	7	6	2	17
TOTAL	60 (4.1%)	262 (17.7%)	649 (43.9%)	506 (34.3%)	1477

A total of 722 abstracts from presentations at EAST, WTA and AAST were identified. After excluding basic science abstracts, 498 abstracts were reviewed. Results of the abstract review are summarized in Table 5. There were 36 (7.2%) class I and 197 (39.6%) class II abstracts presented at these national meetings. The majority (53.2%) of abstracts presented were categorized as class III or IV. During the period reviewed, the largest proportion of class I abstracts was presented at EAST (9.2%). At WTA and AAST, the proportion of class I abstract presentations was 6.1% and 6.8% respectively.

Figure 5

Table 5: Classification of presented abstracts

MEETING	Class I	Class II	Class III	Class IV	TOTAL
EAST	11	57	51	0	119
WTA	7	36	71	1	115
AAST	18	104	140	2	264
TOTAL	36 (7.2%)	197 (39.6%)	262 (52.6%)	3 (0.6%)	498

DISCUSSION

The Institute of Medicine has defined clinical practice guidelines as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.[6] In the face of a rapid and ever-expanding medical "pool of knowledge", guidelines also help clinicians stay current with state-of-the art management in their respective specialties.[7,8] The resource-intense nature of trauma care makes PMGs particularly appealing for practicing traumatologists. Theoretically, by reducing variation in provider-specific practice patterns, directing services more appropriately and guiding the allocation of precious resources, PMGs can have a beneficial effect on health care expenditures. Moreover, as predicted by Rhodes in his 1994 EAST Presidential Address, healthcare policymakers and third-party payors may eventually mandate practice parameters for trauma care. Thus, PMGs may be essential as trauma centers attempt to survive in the modern medical-economic environment.[9]

The utility of any PMG is proportional to its validity.8 Scientific validity for any guideline is derived through evidence-based medicine, whereby the current best evidence from clinical care research is used to manage individual patients.[10] The process requires that all literature specific to a given topic be reviewed and classified based on its scientific quality. Recommendations for management are subsequently formulated based on the number of studies and scientific value of literature in each class.3 A formal methodology for data classification was first offered by both Canadian and U.S. Preventative Service Task Forces.[11,12] The methodology has been modified somewhat as described by the EAST Ad Hod Committee on Guideline Development.3

As described above, there is a relative deficiency of class I data concerning care of the trauma patient. Only 4.1% of the articles reviewed were determined to represent class I data. An additional 17.7% were class II articles. The Journal of Trauma (the official journal of the AAST, EAST, WTA and Trauma Association of Canada) is far and away the leading source of scientific trauma literature, with over 1100 citations identified over the 43-month period of this review. Still, the 32 class I articles only represent 2.9% of the total number of articles published in this journal. While other journals may have a higher proportion of class I articles, their numbers are quite small when compared to the Journal of Trauma.

There are several plausible explanations for the deficiency of class I data in trauma. Multiple injuries combined with a variety of confounding premorbid factors make the trauma patient a heterogenous "system". As a result, isolation of a discrete number of variables for well-designed scientific trials is quite complex. In addition, the primary goal in the unstable trauma patient (i.e. rapid evaluation, vigorous resuscitation and immediate access to definitive surgical care) is contradictious to class I research. There are obvious logistical and ethical impediments to including this group of patients in randomized controlled trials. In patients who are obtunded or unconscious, informed consent for enrollment in prospective clinical trials may be unobtainable. Although implied consent is often employed in such situations, it may not always be appropriate for enrollment into a clinical trial. Finally, the limited availability of funding to support prospective clinical research contributes to the lack of class I studies in trauma.

Despite the paucity of prospective randomized clinical research, the efficacy of implemented PMGs has been demonstrated. In a review of 59 published guidelines, Grimshaw documented a significant change in process of care in 93% and improved patient outcome in 82%.1 Clemmer demonstrated an 87% cost reduction when standard practice protocols were introduced to an ICU population.[13] Recently, Price studied the effect of practice guidelines for management of 6 infectious diseases in surgical ICU patients. Following the implementation of guidelines, patients with infections had a lower mortality (5.6%) compared with similar patients during before the use of guidelines (20%). In addition, the cost of antibiotics was reduced $518.66 per patient.[14] There have been no large studies which demonstrate the efficacy of PMGs specific to trauma.

There are several limitations to this study, most of which are inherent to its subjective design. The literature search was limited to ten journals and the abstracts were selected from presentations at meetings from only three national organizations. Undoubtedly, a number of journals that may publish trauma research were not included. Limiting the search to Medline referenced citations is also an acknowledged source of bias. Fabian recently estimated that Medline contains only 25% of all available published journals.8 Other authors have documented a 51% sensitivity for identifying class I studies using Medline.[15] In addition, the subject headings utilized for the Medline search and the exclusion criteria may have omitted a significant number of quality articles. Finally, a single author reviewed each article. The methodology did not include any measure of interrater reliability specific to classification of evidence.

CONCLUSION

This study documents the relative lack of published and presented prospective randomized studies during a recent time period. More than half of the presentations and the literature reviewed consisted of either retrospective reviews or case reports. These results should not deter the continued development of PMGs for trauma. However they should be considered as regional and national organizations continue to develop guidelines designed to improve clinical care and optimize resource utilization. In order to ensure the acceptance of guidelines by practicing clinicians, efforts should be focused on ensuring their scientific legitimacy.

Future research in trauma should be of the highest quality possible. However, evidence based medicine must acknowledge the value of non-randomized trials and expert opinion to answer those questions for which no prospective randomized trial has been performed.[10,16] Prospective randomized trials are acknowledged as the most valid evidence utilized for guideline development. However, the fact that a study is categorized as class I does not automatically deem it a quality study. Moreover, in lieu of the practical limitations to class I studies in trauma patients, the legitimacy of well-designed class II studies must be taken into account. Class III studies and the majority of class II studies should stimulate further prospective randomized research.8

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