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Prospective Evaluation

Infection Control Practices (Safe Injection and Medication Vial Utilization) for Interventional Techniques: Are They Based on Relative Risk Management or Evidence?

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Background: Recently, multiple regulations and recommendations for safe infection control practices and safe injection and medication vial utilization have been implemented. These include single dose and multi-dose vials for a single patient and regulations. It is a well known fact that transmission of bloodborne pathogens during health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication administration. Multiple case reports have been published illustrating the occurrence of infections in interventional pain management and other minor techniques because of lack of safe injection practices, and noncompliance with other precautions. However, there are no studies or case reports illustrating the transmission of infection due to the use of single dose vials in multiple patients when appropriate precautions are observed. Similarly, the preparation standards for simple procedures such as medial branch blocks or transforaminal epidurals have not been proven to be essential. Further, the effectiveness or necessity of surgical face masks and hats, etc., for interventional techniques has not been proven.

Objective: To assess the rates of infection in patients undergoing interventional techniques.

Study Design: A prospective, non-randomized study of patients undergoing interventional techniques from May 2008 to December 2009.

Study Setting: An interventional pain management practice, a specialty referral center, a private practice setting in the United States.

Methods: All patients presenting for interventional techniques from May 2008 to December 2009 are included with documentation of various complications related to interventional techniques including infection.

Results: May 2008 to December 2009 a total of 3,179 patients underwent 12,000 encounters with 18,472 procedures.

A total of 12 patients reported suspicion of infection. All of them were evaluated by a physician and only one of them was a superficial infection due to the patient's poor hygienic practices which required no antibiotic therapy.

Limitations: Limitations include the nonrandomized observational nature of the study.

Conclusion: There were no infections of any significance noted in approximately 3,200 patients with over 18,000 procedures performed during a 20 month period in an ambulatory surgery center utilizing simple precautions for clean procedures with the use of single dose vials for multiple patients and using safe injection practices.

Clinical Trial Registrion: NCT00625248

Key words: Interventional pain management, interventional techniques, complications, infection, safe injection practices, single dose vials, multi-dose vials, surgical face masks, relative risk.

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Of the numerous regulations controlling the practice of medicine in the United States (1-6), infection control practices including safe injection and medication vial utilization are among some of the most burdensome and expensive (7-13). There are no dissenting opinions that transmission of bloodborne pathogens during health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication administration by health care professionals in various clinical settings, not only in the United States, but across the globe (7,14-22). These reports also include interventional pain management practices (7,14,23-26). Consequently, multiple guidelines and regulations have been developed and imposed (7,10-13). However, these guidelines are far from being evidence-based and may be based only on relative risk reduction or many other factors.

Clinical guidelines are a constructive response to the reality that practicing physicians and other providers require assistance for assimilating and applying the exponentially expanding, often contradictory, body of medical knowledge (27). Ideally, specific clinical recommendations contained within guidelines are systematically developed by expert panels who have an understanding of the clinical problem, have clinical experience with the procedures, or interventions being assessed, understand relevant research methods, and are able to make considered, reasonable judgements. However, multiple guidelines, including those proposed by regulations derived from multiple organizations with their own individual agendas and conflicts, are based either on no evidence or single case reports and raise issues of concern in the United States (7,10-13).

The issue of conflicting guidelines results from many recent publications. In a recent publication it was illustrated that adverse events in hospitals based on Institute of Medicine (IOM) standards do not accurately measure them (28). Utilizing a new and sensitive tool after many years and much expense illustrated not only that the extensive measures proposed by IOM standards have not improved care by reducing the number of adverse events in hospitals, but adverse events in hospitals may be 10 times greater than previously measured (28). IOM also has published multiple new guidelines for the preparation of guidelines (29,30). An important example of guideline debate relates to infection control and the role of comparative effectiveness research (CER). A commentary (8) about infection prevention in CER described that health care-acquired infections, particularly those due to antimicrobial-resistant bacteria, have received significant attention in recent years.

In fact, as of 2011, it has been shown that an evidence-based intervention bundle did not reduce surgical site infection (SSI) (31,32). They concluded that bundling of interventions, even when the constitutive interventions have been individually tested, does not have a predictable effect on outcome (31). The overall rate of SSI was 45% in the extended arm of the study and 25% in the standard arm. In another study of intervention to reduce transmission of resistant bacteria in intensive care (33), expanded barrier precautions or interventions as compared with the existing practice (control) showed the interventions to be ineffective in reducing the transmission of methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococcus (VRE).

Livingston and McNutt have described the hazards of evidence-based medicine in assessing variations in care (34). They showed issues related to frequently used measures of processes of care by Medicare's 25 quality metrics (35), which in essence may cause harm rather than provide benefit. Traditionally, adherence to these processes is thought to lead to improved outcomes. One such programs is the Surgical Care Improvement Project introduced in 2006, with a goal of reducing surgical complications by 25% by 2010 (36). The project was based on observational studies demonstrating associations between process and outcomes, leading the experts to conclude that adherence to this series of process measures would result in better care. However, for some process measures, studies have shown that adherence to these measures is not necessarily associated with improved outcomes, but may actually be harmful. This has been the case for perioperative antibiotic use and postoperative wound infection (37), and for acute myocardial infarction, heart failure, and pneumonia (38).An additional measure associated with considerable harm, was tight glucose control in critically ill patients (39).

The recommendations for infection control which are universally applied since January 2010 are based on no evidence, single, few or multiple case-reports, inaccurate and incomplete information, and conjecture. While education and other guidelines relating to sanitary environment, traffic flow, environmental conditions related to the monitoring of air flow exchanges infiltration systems for hospitals and ambulatory surgery centers, regular facility cleaning and disinfection, and routine hand washing are essential and common

sense approaches, the regulations about safe injection practices with single-dose and multi-dose vials with one vial per patient, and other recommendations of sterile attire for each and every procedure may be overreaching, expensive and burdensome to the practice of medicine, specifically for closed procedures including interventional techniques, which may ultimately result in reduced access.

Consequently, we sought to assess the risk of infection in patients in a prospective, non-randomized evaluation in patients undergoing interventional techniques, utilizing simple precautions from 2008 through 2009 prior to implementation of the new regulations.

Methods

The study was conducted in the United States in a private interventional pain practice and specialty referral center based on Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (40-42). The Institutional Review Board (IRB) approved the study protocol. The study is registered with the U.S. Clinical Trial Registry NCT00625248. This study was conducted with internal resources of the practice without any external funding either from industry or from elsewhere. The results of this prospective non-randomized study of bleeding risk have been published (43).

Participants

All patients undergoing interventional techniques from May 2008 to December 2009, were included.

Interventions

This study was performed prospectively on patients without change in their normal course of treatment. Thus, the IRB waived the requirements for specific consent for inclusion in the study. However, all the patients were informed about the nature of the study with adherence to all confidentiality and Health Insurance Portability and Accountability Act (HIPAA) requirements.

Pre-Enrollment Evaluation

The patients provided their history of medical issues, antithrombotic therapy, and previous experience from interventions.

Inclusion and Exclusion Criteria

All the patients receiving interventional techniques during the time period were included, except those undergoing disc decompression procedures and intrathecal implantables.

Description of Interventions

Either diagnostic or therapeutic interventional techniques of various types were performed on all participants. The procedures were performed by 3 physicians in sterile operating rooms located in an ambulatory surgery center, using fluoroscopy except for intraarticular injections and peripheral nerve blocks.

At this ambulatory surgery center, over 100,000 interventional techniques were performed until 2008. The routine has been maintaining a sanitary environment; appropriate injection practices without contamination, even though single-dose vials were utilized for multiple patients; preparation of intravenous fluids in advance, which were left for maximum of 4 hours either before or after noon; and use of multi-dose vials for one week stored at appropriate temperatures. The sterile preparation included appropriate scrub with sterile solution and coverage of the area and performance of the procedure with sterile gloves for all epidural injections. For neurotomy procedures and adhesiolysis, extensive sterile preparation was carried out and sterile gowns were worn, however, without a mask and hat. For facet joint nerve blocks, transforaminal epidurals, sympathetic blocks, and peripheral nerve blocks, site preparation was with alcohol prep without draping and using a no touch technique with non-sterile gloves. For intradiscal procedures, endoscopic adhesiolysis, and implantables, full precautions were taken including hat, mask, gown, sterile gloves, and antibiotic administration. Antibiotic administration was also provided for percutaneous adhesiolysis.

Objective

To investigate the risk of infection in patients undergoing various types of interventional techniques in managing chronic pain under usual circumstances.

Outcomes

Eight nurses were trained to evaluate the various adverse events with interventional techniques including infection. Each participant was contacted postoperatively within 48 hours. Measurable outcomes employed were any signs of infection including rash, swelling, abscess formation, or fever. Any patient with signs of infection or any other problem were further followed including follow-up by the physician. In addition, patients also were instructed to call and report any problems related to the procedures performed without any time limit.

Statistical Analysis

Data were recorded in a database using Microsoft Access (Microsoft Corporation, Redmond, WA) by a person not participating in the study. The SPSS 9.0 statistical package (IBM Corporation, Armok, NY) was used to generate the frequency tables. Pearson chi-square test was carried out in the comparisons of proportion between antithrombotic with no antithrombotic. Results were considered statistically significant if the P value was less than 0.05.

Results

Participant Flow

Table 1 illustrates the baseline characteristics. The study period lasted from May 2008 to December 2009 (20 months) with a total number of participants of 3,179 with 12,000 encounters and 18,472 procedures.

Procedural Characteristics

Total number of epidural procedures was 10,261, facet joint interventions were 7,482 (multiple levels and/or bilateral), and other procedures were 729 of which 199 were sacroiliac joint interventions, 114 were lumbar sympathetic blocks, 150 were stellate ganglion blocks, and the remaining were intercostal nerve blocks, occipital nerve blocks, intraarticular injections, and peripheral nerve blocks.

Incidence of Infection and Follow-up

Patients were evaluated for multiple parameters of adverse effects related to the injection therapy including bleeding, hematoma, etc., along with infection. A total of 12 patients reported suspicion of infection. All of them were evaluated by a physician and only one of them was a superficial infection as the patient failed to maintain proper hygiene and scratched the site. Even then no antibiotics were given. All others were provided with reassurance and also were advised to keep the areas of interventions clean.

Table 1. *Patient demographics based on encounter.*

Gender	Male	36.1% (4,336)
	Female	63.9% (7,664)
Age	Mean ± SD	50.5 ± 13.00
Height	Mean ± SD	65.8 ± 7.95
Weight	Mean ± SD	184.2 ± 54.94
Smoking	Yes	59.4% (7,124)
	Quit	4.3% (518)
	None	36.3% (4,358)
Antithrombotic	Yes	25.7% (3,087)
	Discontinued	44.6% (1,376)
	Continued	55.4% (1,711)

Discussion

After evaluation of approximately 3,200 patients with 12,000 encounters and over 18,000 procedures, this prospective non-randomized evaluation illustrated only one superficial infection due to patient's unhygienic behavior, among a total of 12 suspected infections reported by the patients, with none of them requiring antibiotic treatment or any other treatment. This is the first prospective evaluation prior to implementation of safe injection practices including single-dose and multi-dose vials to be utilized only on one patient. Further, this evaluation also utilized simple common-sense precautions for clean procedures.

It is well publicized that breeches in safe injection, infusion, and medication administration will continue to result in a significant complication rate. The literature is replete with multiple outbreaks resulting in exposure of over 100,000 individuals to viral hepatitis and the transmission of either hepatitis B virus (HBV), or Hepatitis C virus (HCV) to more than 500 patients (22). The unsafe practices used by health care personnel in these outbreaks have been categorized to include: syringe reuse between patients during parenteral medication administered to multiple patients; contamination of medication vials or intravenous bags after having been accessed with a used syringe and/or needle; failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients; and inappropriate care maintenance of finger stick devices and glucometer equipment between use on multiple patients. However, none were related to the use of single dose vials accompanied by safe injection practices.

Consequently, with the assistance of multiple organizations, various recommendations and regulations have been advanced for infection control. While these regulations may be appropriate for open surgical procedures, they may be burdensome, expensive and without proven benefit for multiple procedures including those of interventional techniques, endoscopy procedures, and other injection procedures. Generally, surgical procedures are defined as sterile or clean. The ma-

jority of the interventional techniques are classified as clean procedures except for intradiscal procedures and implantables. Thus, many procedures are performed utilizing single dose vials for multiple patients, extensive sterile preparation is not carried out, and attire does not include mask, hat, and changing of shoe covers for each patient by each member of the team. In fact, a coalition of 2,500 U.S. hospitals has pushed for safe infection practices (44). The discussion has focused on the fact that more education and research and superior product designs are needed to end unsafe injection practices that have led to 30 infectious disease outbreaks in the last 10 years, resulting in more than 125,000 patients with potential exposure to infectious diseases such as hepatitis C due to reuse of syringes. Consequently, these are considered as largely preventable medical errors and similar to wrong side surgery. The data reported by the National Healthcare Safety Network (NHSN) indicate that the median SSI rates following herniorrhaphy were 0.74% to 2.42% for low risk operations and 5.25% for high risk procedures, whereas for breast surgery, the median SSI rates were even higher, 0.95% to 2.95% for low risk and 6.36% for high risk cases, respectively (45).

There are no controlled, randomized, or even prospective studies illustrating the infection rate for interventional techniques. However, there are multiple case reports (23-25,31,32,45-47). These case reports have focused on various aspects, but applied regulations may not correlate with the findings. In 2007, guidelines for transparent reporting of outbreak reports and intervention studies of nosocomial infection were published (48). This report insisted that the quality of research in hospital epidemiology (infection control) must be improved to be robust enough to influence policy and practice. They in fact suggested that the publications must be performed utilizing Consolidated Standards of Reporting Trials (CONSORT) statement, which sought to improve the quality of reports of randomized control trials (49). They also advised that observational studies must follow the current STROBE initiative, especially for cohort, case-control, and cross-sectional studies (42).

In an evaluation of central nervous system infections after interventional pain management procedures, Cohen et al (23) suggested contamination of common medications, likely contrast solution, as the source of outbreak. They identified 5 culture-confirmed case-patients and 2 presumptive case-patients who had no bacteria recovered from culture. These 7 case-patients were compared with 28 controls who underwent procedures at the same clinic but did not develop symptoms of infection. They reported that no breaches in infection control were observed in hand hygiene, sterile preparation, or barrier precautions (23). However, multiple medications were accessed with a common needle and syringe during each procedure. Thus, infection with Serratia marcescens was traced. Previous reports of health care associated outbreaks had included injected medications (15-25,46).

In another report of an outbreak of Klebsiella pneumoniae and Aerogenes bacteremia after interventional pain management procedures in New York City in 2008, Wong et al (26) identified 4 laboratory-confirmed case-patients, 3 with Klebsiella pneumoniae and one with Enterobacterial aerogenes, and 5 suspect case patients. They concluded that infection was associated with pain management procedures, specifically those involving injections to the sacroiliac joint. Lapses in infection control were likely from contamination of single-use vials that were used for multiple patients. Thus, they recommended that reuse of medication vials should be restricted and affordable single-dose vials should be made available, which has not been accepted by the drug industry, even though regulation was implemented. This pain management facility shared space with another medical practice and included 3 rooms. Described opportunities for bacterial contamination included lack of hand hygiene before procedures, not wearing appropriate personal protective equipment during the procedure (i.e., cap, gown, and mask), the injection site was not properly cleaned, single-dose medication vials were used for multiple patients, medication vials were not labeled with date opened, and opened vials were not universally stored in the refrigerator between facility days. Authorities also stated that the spinal needles were bent by a gloved hand; stylets were not replaced during prolonged procedures and were reinserted into the same patient; the equipment used during procedures (e.g., lead aprons) was not properly disinfected between procedures and was reported to be rarely cleansed. Immediate recommendations included suspending the use of single-dose medication vials for multiple patients and improvement of standard infection and control patients. These breaches have been essentially considered to be a universal phenomenon even though most were limited to this facility without safe injection practices and were not the common or standard practices in interventional pain management. Nevertheless, the federal government has accepted these recommendations and they have been

made universal. Further, there was no evidence in any of the cases that a single dose vial properly used for multiple patients with sterile precautions had caused any infections. Consequently, Datta et al (50) raised numerous questions about this report, but Weiss (51) essentially brushed off the issues, stating that Datta et al (50) were missing the big picture and cost should not be a factor and then quoted multiple references which were not related to proper infection control practices or usage of single dose vials.

Surveys of anesthesiologists (52), interventional radiologists (53) and neurologists (54) found apparently substantial lapses in infection control during injections. Thus, face masks, caps, and other apparel have been recommended to be worn and changed for each patient. However, none of the infections have been irrefutably attributed to face masks, caps, or use of single-dose vials when appropriate precautions have been taken (12,55-58). Evaluation of evidence for surgical face masks illustrates that it is not clear that wearing surgical face masks harms or benefits the patients undergoing elective surgery (55-57). It appears that unsanitary environment, coupled with reuse of needles, appears to be the major cause rather than single-dose vials appropriately used for multiple patients or other factors.

Specific infection control measures have been introduced to reduce infection associated with implantable pain therapy devices (59), and spinal infections including various measures spanning from preoperative, intraoperative, to postoperative measures in addition to standardized prophylaxis (60). In a systematic review of the influence of perioperative risk factors in therapeutic interventions on infection rates after spine surgery (61) it was concluded that causes of postoperative spinal site infections were multifactorial and related to a complex interplay of patient and procedural influences. Of the surgical adjuncts investigated, only irrigation with dilute Betadine solution showed moderate support for reducing infection rates. The report of Surgical Care Improvement Project which aims to reduce surgical infectious complications rates through measurements and reporting, has concluded that the adherence reported on individual surgical care improvement project measures, which is the only form in which performance is publically reported, was not associated with a significantly lower probability of infection (37). Further, a universal, rapid MRSA admission screening strategy also did not reduce nosocomial MRSA infection in a surgical department with endemic MRSA prevalence, but relatively low rates of MRSA infection (62).

The surveyors from CMS using an audit tool assessed compliance with specific infection control practices in 68 ASCs (63). They focused on 5 areas of infection control: hand hygiene, injection safety and medication handling, equipment reprocessing, environmental cleaning, and handling of blood glucose monitoring equipment. The results illustrated that 46 of the 68 ASCs or 67.6% had at least one lapse in infection control, 18% of ASCs had lapses identified in 3 or more of the 5 infection control categories. Common lapses included using single-dose medication vials for more than one patient at 28% of the centers, failing to adhere to recommended practices regarding reprocessing of equipment at 28% of the centers, and lapses in handling of blood glucose monitoring equipment at 46% of the centers. Further analysis illustrated that pain management procedures were provided at 26 of the 67 surveyed centers with 13 of 20 centers in Oklahoma compared to 6 of 15 in North Carolina, and 7 of 32 in Maryland. In an editorial (64) these practices were justifiably condemned, but no causal relationship has been established since there were no infections.

At the Ambulatory Surgery Center, in the current study, over 100,000 interventional procedures were performed without any significant infections. Using proper precautions and simple infection control measures, it has been shown that there is no significant risk with the use of single-dose vials for multiple patients and multi-dose vials used over a period of one week. However, changing to prepping and scrubbing each patient for each procedure, using face masks and hats by all personnel in the operating room and changing them for each patient, using single-dose vials, specifically for non-iodinated contrast and other drugs will be extremely expensive (as much as 400% increase in costs) and also has the environmental risks disposal of the unused drugs. Further, it appears that the drug industry will not change their manufacturing patterns, and sometimes smaller single-dose vials are more expensive than larger single-dose vials, even though expense regulations have been enforced.

The limitations of this study include its prospective nature, and being a single center study even though a large number of patients were included. However, this is the only study available in the literature to assess infections for interventional techniques and the result is almost a zero prevalence.

Thus, extensive, expensive, and burdensome restrictions may result in reduced access to interventional tech-

niques. Interventional techniques have been escalating in their utilization over the past several years (65), and even though the effectiveness of multiple interventional techniques has been debated (66-74), they are widely used with moderate evidence of their effectiveness presented from randomized trials (75-90), systematic reviews (91-98), guidelines (99,100), and expert consensus.

Conclusion

Infection control practices for interventional pain procedures utilizing simple precautions, the no touch technique, and single dose vials with safe injection practices are safe and without risk of infection based on the study results of 18,000 procedures over a period of 20 months.

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