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QUESTION 3: Does the pressure of the pulsatile delivery mechanism for irrigation fluid influence the efficacy of the irrigation solution to eradicate infecting organisms in the wound?

RECOMMENDATION: A series of clinical studies have been unable to observe differences in clinical outcomes or reoperation rates between high-pressure vs. low-pressure wound irrigation. Tangential hydrosurgery is an emerging irrigation method that, though promising, still requires further investigation.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 90%, Disagree: 4%, Abstain: 6% (Super Majority, Strong Consensus)

RATIONALE

There has been a combination of in vitro models, animal models and clinical studies that have investigated the efficacy of irrigation pressure in wounds. The majority of the in vitro and in vivo studies have been completed in regards to traumatic wound debridement. These studies have looked at the ability of irrigation methods to remove bacteria, inorganic contaminate, tissue damage induced from irrigation and possible differences in distribution of contaminate in the wound after irrigation. A series of clinical studies have been completed that do not demonstrate any difference in clinical efficacy between high-pressure and low-pressure irrigation.

High and low-pressure lavage has mixed results in removing contaminants from the wound. In vitro studies have shown an increased ability of pulsatile lavage to remove inorganic debris [1,2] and bacteria [3]. Animal models have had indeterminate results. In a rabbit animal model, high-pressure irrigation and bulb syringe irrigation were equally as effective at removing debris. In an animal model using bioluminescent bacteria, high-pressure lavage demonstrated an increased ability to remove bacteria [4].

Concerns have been raised that high-pressure irrigation may distribute contaminates deeper into soft tissues. Paradoxical results that high-pressure irrigations have fewer contaminants removed support these results [5,6]. This data is supported by luminescent bacteria in wound animal models where high-pressure irrigation has improved or has an equivalent ability to initially remove bacteria, but that there is a higher rebound of bacteria several hours after completion of the procedure [7]. In an in vitro model of a contaminated human tibial fracture, high-pressure pulsatile lavage followed by cultures of serial sections at increasing distance from the fracture site revealed a reproducible pattern of bacterial propagation into the intramedullary canal [8]. In addition, bone destruction was found to vary proportionally with the depth into the canal.

There have been a large number of in vitro studies demonstrating possible increased levels of microscopic and macroscopic bone and tissue destruction after high-pressure pulse lavage as compared to low-pressure irrigation. On bone specimens, high-pressure pulse lavage was associated with more fissures and defects in cancellous bone [3], bone structure and fracture healing [3,9]. Similar results have been seen with high-pressure irrigation having increased gross damage to soft tissue as compared to low-pressure irrigation [1,5,10]. These results show that high-pressure pulsatile lavage penetrates and disrupts soft tissue to a deeper level than low-pressure lavage, causing considerable gross and microscopic tissue disruption [5].

Animal models support the findings from these in vitro models. High-pressure lavage can inhibit early new bone formation in an intraarticular fracture rabbit model. There was a direct relationship between irrigation pressures and the amount of cellular materials removed from the trabeculae at the irrigation site [11]. Animal models have shown that high-pressure pulsatile lavage of musculoskeletal wounds can cause injury to tissue, resulting in myonecrosis and dystrophic calcification [12]. High-pressure pulsatile lavage has also been shown to significantly decrease the mechanical strength of fracture callus (peak bending force and stiffness) during the early phases of healing (three weeks), as compared to bulb syringe techniques in a non-contaminated diaphyseal femoral fracture model in rats [13].

Multiple clinical studies have demonstrated that high or low-irrigation pressure results in similar clinical outcomes. The largest of these was the Fluid Lavage of Open Wounds (FLOW) study [14]. This was a large, well-designed, prospective, randomized, two-by-three factorial design clinical study comparing three irrigation pressures and two irrigation solutions (normal saline and castile soap). A total of 2,551 patients were enrolled and the primary end-points were reoperation within 12 months from the index procedure or treatment of a wound infection. The FLOW study demonstrated that the rates of reoperation were similar regardless of irrigation pressure (ClinicalTrials.gov NCT00788398) [14].

These findings are supported by several smaller studies. The FLOW study design was based on pilot data that suggested that low pressure irrigation of open wounds may decrease reoperation rates for infection, although the pilot study did not observe any statistically significant differences between high and low pressure irrigation groups (ClinicalTrials.gov NCT01069315) [15]. In a small prospective randomized clinical study of acute periprosthetic joint infection, there were no differences seen with the use of high versus low-pressure irrigation with outcomes defined by retention of prosthesis or elevation of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) at one year [16].

Irrigation pressures may have difficulty removing bacteria from the wound because biofilm acts as a viscous fluid. Biofilms are viscoelastic and resist detachment from increased fluid flow and shear by deformation. This allows the biofilm to remain attached to the surface, or roll along a surface in response to a shear stress from fluid [17]. Given this limitation of pulsatile irrigation as well as the concerns for bone destruction discussed above, there has been a recent interest in exploring novel delivery mechanisms of the irrigation fluid. In a prospective randomized control study, tangential hydrosurgery was compared to standard surgical debridement of grade IIIA and IIIB open tibia fractures in 40 patients. It was found that when hydrosurgery was used, significantly fewer debridement procedures were required prior to final wound closure [18]. Hydrosurgery debridement was also evaluated as a method for removing bacteria from fracture implants. Specifically, when comparing the use of hydrosurgery, pressurized pulsatile lavage and bulb syringe to deliver the same volume of saline to debride *Staphylococcus aureus*-contaminated stainless-steel fracture plates, residual bacterial loads were found to be significantly lower in the hydrosurgery group [19].

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