SH30: Should a negative control sample be sent at the time of revision surgery?

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Supportive Delegates: Akshay Krishnan

Response: The available data does not support sending a negative control sample as routine practice at the time of revision shoulder arthroplasty.

Strength of Recommendation: Limited

Delegate Vote: 54 (100%) agree; 0 disagree; 0 abstain

Rationale: A comprehensive literature review was performed on PubMed and through the Journal of Shoulder and Elbow Surgery to identify all studies within the last 5 years that discussed the use of a negative control sample at time of revision shoulder arthroplasty. Only 1 study was identified through the Journal of Shoulder and Elbow Surgery. A second study was identified through references. An expanded search was performed to identify literature that assessed the use of negative control samples taken during revision total hip or total knee arthroplasty. No additional studies were found. Given the lack of available studies, our assessment for use of a negative control was based on the two studies discussed below.

The use of a negative control sample at time of revision surgery has been considered as a way to validate positive or negative intra-operative culture results of *C. acnes* given the potential for a positive culture resulting secondary to contamination. Unfortunately, there is a paucity of literature available in shoulder, hip, or knee arthroplasty to validate whether or not this is an efficacious practice. Namdari et al in 2020 performed a prospective cohort study where swabs were taken during primary shoulder arthroplasty. Two sterile swabs were exposed to air and returned to their containers. One was sent to their institution's microbiology lab and the other was sent for next generation sequencing (NGS) in Lubbock, TX. Forty consecutive swabs were analyzed and *C. acnes* was identified in 6/40 while coagulase negative staph was identified in 3/40. No signs of clinical infection were identified in the shoulder arthroplasty cases at the end of 90 days. These findings indicate that contamination could even occur within the air of the operating room.

Another study evaluating the use of negative controls at time of surgery was performed in 2022 by the ASES PJI Multicenter Group. In this study by Hsu et al, 11insttitutions participated and each provided 10 positive control (PC) and 2 negative control (NC) samples. All PC samples were taken from a failed shoulder arthroplasty with confirmed *C. acnes* and probable PJI per MSIS criteria. The authors found that average time to culture growth was a statistically significant factor between PC (4.0 days +/- 1.3) and NC samples (8.3 days +/- 5.1). This significant difference in time to growth could represent the likelihood that positive culture growth in the NC group is secondary to contamination from specimen handling. The authors also found that 14% of NC samples had positive cultures. This rate is referred to the "false positive" rate. When compared to other studies performed by Mook et al (13%) or Namdari et al (15-20%), their rates are comparable. Unfortunately, this study did have limitations in that there was

no consistency between institutions with regards to laboratory protocols, specimen handling, or incubation periods. Given this, it is difficult to determine the significance of this false positive rate and if the variations in NC positive cultures are simply due to institution-specific factors. In summation, although these two studies demonstrate that NC samples can still return positive culture results, the clinical utility of this remains unclear. Given this, we cannot make a recommendation for or against use of NC samples as a routine practice at time of revision shoulder arthroplasty. It is recommended for surgeons to work with their infectious disease colleagues and laboratory staff to understand the false positive rate at their specific institution in order to better interpret operative culture results, as even in a non-infected shoulder there is likely a 15-20% chance of a positive culture.

For example, if a surgeon takes 5 cultures, the likelihood of having at least one false positive culture for C. Acnes is 67.2% if the false positive rate is 20%. If 2 cultures turn positive, the chance they are both false positives drops to 20.5%, and with 3 positive cultures the chance they are all false positives is on 5.1%. Some surgeons have advocated for taking more than 5 cultures. With 7 cultures taken and a 20% false positive rate, the probabilities are: at least one false positive: 79.0%, 2 false positives: 27.5%, and 3 false positives: 11.5%.
Therefore, the surgeon should be wary of declaring infection based on 1 positive culture result.

References:

1. Hsu JE, Bumgarner RE, Bourassa LA, et al. What do positive and negative cutibacterium culture results in periprosthetic shoulder infection mean? A multi-institutional control study. *Journal of Shoulder and Elbow Surgery*. 2022;31(8):1713-1720. doi:10.1016/j.jse.2022.01.127
2. Namdari S, Nicholson T, Parvizi J. Cutibacterium acnes is isolated from air swabs: time to doubt the value of traditional cultures in shoulder surgery? Arch Bone Jt Surg 2020;8:506-10. https://doi.org/ 10.22038/abjs.2020.40642.2095