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QUESTION 2: What is the relevance of unexpected positive cultures (UPC) in revision shoulder arthroplasty without clinical or radiographic signs of infection?

RECOMMENDATION: The relevance of unexpected positive cultures is unknown.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 100%, Disagree: 0%, Abstain: 0% (Unanimous, Strongest Consensus)

RATIONALE

A comprehensive literature review was performed to identify all studies on UPC in shoulders undergoing revision arthroplasty. Searches for the terms "unexpected," "infection," "positive culture," "indolent infection," "gram-positive bacterial infections," "prosthesis-related infections" and "shoulder joint," "shoulder," "arthroplasty," "total joint," "replacement," "periprosthetic," "peri-implant," "shoulder prosthesis" were performed using the search engines PubMed, Embase and Scopus. These searches were conducted on February 2, 2018 and include results published through that time. Inclusion criteria were patients undergoing revision shoulder arthroplasty, with no clinical or radiographic signs of infection, who had positive cultures taken from the shoulder undergoing the revision. Only studies that focused on the potential relevance of these UPCs were included. Only English-language studies that presented original data on more than five patients meeting inclusion criteria were included. For articles with both unexpected positive cultures and known septic revisions, the patients with UPC were included in the review if the data were reported such that patients meeting inclusion could be separated. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria were followed. Fifteen articles met inclusion and exclusion criteria.

At the time of the writing of this document, the definition of a UPC in shoulder arthroplasty revisions has not been fully elucidated, nor has the role of *Cutibacterium acnes*, a commonly identified microorganism. Few studies have been designed to adequately capture this phenomenon as defined above by the inclusion and exclusion criteria, resulting in a challenge to draw any definitive conclusions. The results of studies that report the frequency of UPC and their characteristics are summarized in Table 1 [1–14]. An additional study [15] was also returned that does not provide data appropriate for Table 1, but nonetheless was relevant to this question and is discussed below.

Few studies fully meet the defined inclusion and exclusion criteria, and little consistency exists on the definitions of "unexpected" or even what constitutes a "true positive" culture. Without agreement on this definition, it is exceedingly challenging to compare studies reporting these rates. In some studies, "true positive" was defined as a shoulder that required re-revision whereas in other studies, evidence of an overt infection postoperatively was used. While both outcomes are clinically significant, the association of positive cultures with them cannot be conclusively characterized as causal.

The studies that identified UPC in shoulder arthroplasty revisions report a range from 9–56% of cases [5,6]. Combining the rates of UPCs in these studies yields an incidence of 22.5% (305 UPC out of 1,354 shoulder arthroplasty revisions). *C. acnes* was identified in 53.8% (164 of 305) [2,3,5,7,8,13,14]. The results presented by Pottinger et al. [6] were not included in these sums as the same data was included in Lucas et al. [13].

Other reports that did not evaluate UPCs in the setting of shoulder arthroplasty revision but did address the relevance and the baseline rate of positive *C. acnes* cultures in shoulders were included in our search results. Mook et al. found that 20.5% of shoulders undergoing open surgery for a variety of conditions had at least one positive culture (83.0% of which were *C. acnes*), but this rate was not significantly different from UPC rates from their control, "sterile" gauze cultures (13.0%) [16]. At this particular institution, the "false positive rate"—defined as the rate of positive cultures for "sterile" gauze sponges—was 20.5%, with the majority positive for *C. acnes*. These numbers should be compared with the overall rate of UPC in revision shoulder arthroplasty found in this review (22.5%) and with 53.8% positive for *C. acnes*. The detection of *C. acnes* on surgical equipment was replicated by Falconer et al. who, immediately after skin incision in shoulder without prior surgery, swabbed the subdermal layer, the surgeon's glove tip, the scalpel blades and the forceps to determine possible vectors for introduction of this bacteria to the deep shoulder. Where cultures are taken, *C. acnes* was detected on at least one of these cultures in 40% of their patients, with the subdermal layer being the most common origin of positive cultures, followed by the surgeon's glove and forceps. The fact that the within-subject positive culture rate of both of these sites was significantly correlated with positive subdermal cultures led the authors to suggest that it is the surgeon's manipulation of skin during a procedure that ultimately causes contamination of the deep shoulder with this organism [17]. Levy et al. similarly found *C. acnes* in 41.8% of shoulders undergoing primary shoulder arthroplasty for osteoarthritis following standard

chlorhexidine preparation and draping. Interestingly, in contrast to Falconer et al., Levy et al. concluded that this bacterium may not be a contaminant, but instead perhaps plays a role in the pathogenesis of glenohumeral arthritis [18].

To further determine if these positive results represent true positive or false positive results, we evaluated the rate of "true" infections using each author's own criteria. However, these definitions were not consistent across studies, presenting an obstacle that requires the clinician to use his or her judgment as to the most appropriate definition of true infection until a standard definition can be established. In some studies, repeat culture taken at either re-revision or as part of follow-up that demonstrates presence of the same organism was required to define a UPC as a true infection [7–9]. In other studies, signs or symptoms of infection post-revision were sufficient [5,14]. With this methodological caveat regarding the lack of a consistent definition for infection in mind, five studies [3,5,7,8,14] reported a "true" infection rate. When combined, only 18 of 168 total UPCs (10.7%) were considered "true," and, of those 18, 14 (77.8%) were *C. acnes*.

To determine the likelihood that UPCs represent a contaminant, McGoldrick et al. examined 148 cases to identify 14 shoulders with a UPC on revision that occurred at least 3 years following the initial arthroplasty with a mean time to revision of 8 years (range 4–12). They found that 79% of the 109 cultures they obtained grew *Cutibacterium* and concluded that a percentage this high implies that these cultures represent true infections of the shoulder and not contamination. McGoldrick et al. also pointed out that these positive cultures should truly be considered "unexpected" as many of the patients had factors well known to be correlated with positive *C. acnes* cultures, such as male gender, pain and stiffness [10].

Frangiamore et al. evaluated the time to positive culture in an attempt to differentiate "probable true positives" from "probable contaminants." Using their definitions, they found that the cultures of "probable true positives" grew bacteria by 11 days. Conversely, 44% of cultures of "probable contaminant" cases became positive after 11 days. The median time to growth among "probable true positives" was five days, compared to the nine days for the "probable contaminants." Their conclusion points out a potential downside to the increased sensitivity of long-hold cultures for *C. acnes* – this may also come with an increased risk of contamination and false positives. However, again, without a clear definition or a confirmatory test, it is not clear if the late growth cultures were really contaminants or simply had a lower inoculum of bacteria [9].

Pottinger et al. [6] evaluated potential risk factors for UPC in shoulder arthroplasty revisions across three phases of management: preoperative findings, gross intraoperative inspection upon entering the shoulder and histological examination. On multivariate analysis, they found that male sex (odds ratio (OR) 6.41, 95% confidence interval (CI) 3.10 – 14.42), and humeral osteolysis on X-ray (OR 12.85, 95% CI 2.92 – 92.53) were significantly more likely to grow *C. acnes,* while individuals with diabetes (OR 2.80, 95% CI 1.20 – 6.64), a history of smoking (OR 2.88, 95% CI 1.27-6.62) and glenoid loosening on X-ray (OR 3.07, 95% CI 1.50 – 6.40) had increased odds of positive cultures with non-*C. acnes* bacteria. In addition, the presence of a membrane and cloudy fluid were associated with *C. acnes,* while glenoid loosening and chronic inflammatory signs on histology were predictive of UPCs with other bacteria. Increased numbers of cultures taken were associated with UPCs of both *C. acnes* and other bacteria [6].

Factors that were not significant predictors of either type of UPC included local and systemic symptoms, age, white blood cell count, erythrocyte sedimentation rate, C-reactive protein, acne, diabetes and a number of other medical conditions [6]. The number of prior surgeries was not found to be a predictor of UPC [6]. These findings contrast with the findings of Foruria et al. that patients with "true infections" had undergone significantly more previous operations than their "contaminant" cohort [8]. Further complicating the interpretation of UPCs is the difference across studies between the requisite number of cultures with growth for the shoulder to be included in analysis. While some authors require at least two UPCs [4,10,12], others, such as Grosso et al. [5] and Foruria et al. [8], included patients with as few as one positive culture. However, they found that the number of positive cultures was not associated with rate of "true" infection, as they define it. Their data does demonstrate, though, that, when positive cultures are unexpected, the majority of the shoulders only grow out in just one culture (76 of 107 patients), although this finding is clouded by the wide variation in the total number of samples taken per patient (93 of the 107 patients had 1–3 samples taken) [8].

While some authors have conjectured that scenarios where only a small number of cultures grow *C. acnes*, especially with a delayed incubation time [9], are more likely to represent a contaminant [4,16], other authors have noted that these may simply represent a lower quantity of bacteria present. Ahsan et al. introduced a semi-quantitative approach to assessing the bacterial load in an attempt to define a threshold to differentiate "true" infections from "contaminant." They recommended calculating a "Shoulder Propi Value" to represent the amount of growth per culture, combining these values into "Shoulder Propi Scores" for each specimen location, and then calculating the "Average Shoulder Propi Scores." They did not observe a threshold above which one could be confident that a culture was a true positive, and they highlighted the wide variation in culture results across specimen locations [15].

When considering the relevance of UPCs in the context of "true infections," there are two potential areas of clinical significance: the UPC may have been a subclinical pathogenic cause of the revision during which it was uncovered, or the UPC may go on to cause sequelae post-revision. Lucas et al. analyzed the former question in a study evaluating cultures taken from several sites within the shoulder. When considering UPCs from explanted glenoid components of the original arthroplasty, more of these components were loose at revision than were not. However, when considering all the cultures taken from a shoulder, there was no difference between the positive culture rates between the loose and not loose glenoid component groups [13]. In a study examining patients with glenoid component loosening but no evidence of infection otherwise, Cheung et al. evaluated the significance of UPCs both as potentially correlated with the need for the index revision where the UPC was identified and as potentially correlated with the need for future revision. They found that culture results were not associated with the need for the index revision, but they did note a trend towards a positive effect between UPCs and the need for further re-operation, though this did not reach significance ($p = 0.09$) [2].

There is no consistent definition that determines whether a positive culture represents a "true infection" or a "contaminant." One additional state exists; a positive culture could represent "commensal organisms"—present but not causing pain or pathology. Furthermore, while *C. acnes* represents the majority of positive UPC cultures, it is not clear if the relevance of a UPC with one bacterium differs from a UPC with another. The debate regarding the relevance of unexpected positive long-hold cultures will continue until a definition or confirmatory test allows clinicians and researchers to properly categorize these findings.

TABLE 1. Summary of studies examining unexpected positive cultures in shoulder arthroplasty revisions

Author, Year	Proportion of Shoulders with UPC at Revision	*C. acnes* among Patients with UPC	"True" Infections	Definition of "True" Infection	"True" Infection with *C. acnes*	Follow-up (revision/clinical failure) and Organism at that Time
Topolski 2006 [1]	75 UPC reviewed. Total population size is not described.	45/75 (60%)	10/75 (13%)	Required re-revision.	5/10 (50%)	10 total patients required re-revision for pain, instability, dislocation and infection.
Cheung 2008 [2]	20/68 (29%)	14/20 (70%)	Not described	Not described	Not described	Trend toward positive cultures predicting increased likelihood of surgery ($p = 0.09$) in group that did not have glenoid reimplantation. Organism at follow-up not described.
Kelly 2009 [3]	8/28 (29%)	6/8 (75%)	2/8 (25%)	Subsequent infection at minimum 1-year follow-up.	2/2 (100%)	Both infections treated with resection and placement of antibiotic cement spacer. Additional follow-up not described.
Dodson 2010 [4]	6 UPC in retrospective review of 11 patients with positive cultures. Total population size is not described.	6/6 (100%)	3/6 (50%)	Acute and chronic inflammation and granulation consistent with infection on pathology.	3/6 (50%)	All patients chose medical management, but long-term follow-up is not described.
Grosso 2012 [5]	17/187 (9%)	10/17 (59%)	1/17 (6%)	Recurrence with erythema and swelling.	0/1 (0%)	In only patient to develop post-revision infection, irrigation and debridement followed by > 5 weeks of antibiotic therapy successfully maintained aseptic shoulder for at least 5 years. Offending organism was the same as original positive culture, *Staphylococcus epidermidis*.
Pottinger 2012 [6]	108/193 (56%)	75/108 (69%)	Not described	Not described	Not described	Not described
Lorenzetti 2013 [7]	8/55 (15%)	6/8 (75%)	3/8 (38%)	Positive cultures and/or purulence at re-revision.	1/3 (33%)	Of three post-revision infections, all from the control group, *C. acnes* was confirmed in one and underwent re-revision.
Foruria 2013 [8]	107/678 (15%)	68/107 (64%)	11/107 (10%)	Positive culture with same organism as initial culture, taken post-revision, obtained via aspiration or during re-revision.	10/11 (91%)	8 of the 11 true infections underwent re-revision.

TABLE 1. Summary of studies examining unexpected positive cultures in shoulder arthroplasty revisions (*Cont.*)

Author, Year	Proportion of Shoulders with UPC at Revision	*C. acnes* among Patients with UPC	"True" Infections	Definition of "True" Infection	"True" Infection with *C. acnes*	Follow-up (revision/clinical failure) and Organism at that Time
Frangiamore 2015 [9]	26 UPC of 46 studied shoulders, all of which had positive cultures. Total population size is not described.	26/26 (100%)*	17/26 (65%) described as probable true positive	Probable true infection among UPC defined as > 1 positive culture.	17/17 (100%) *	Not described
McGoldrick 2015 [10]	14 UPC at revision at least 3 years after index arthroplasty. Total population size is not described.	14/14 (100%) **	Not described	Not described	Not described	Not described
Piggot 2015 [11]	8 UPC of 24 studied shoulders, all of which had positive cultures. Total population size is not described.	8/8 (100%)*	1/8 (13%)	For UPC, definite infection is defined as at least 2 positive cultures with no other organisms.	1/1 (100%)*	4/8 (50%) UPC had favorable clinical outcome; 3/8 (38%) did not have a favorable clinical outcome, and 1/8 (13%) was lost to follow-up.
Hsu 2016 [12]	27/55 (49%), where "positive" was defined as at least 2 positive Propionibacterium cultures.	27/27 (100%) **	Not described	Not described	Not described	No difference between revision rate, functional or pain scores between positive-culture and control cohorts. 3 from culture-positive cohort underwent re-revision and all cultures were negative at that time.
Lucas 2016 [13] ***	117/221 (53%)	45/117 (38%)	Not described	Not described	Not described	Not described
Padegimas 2017 [14]	28/117 (24%)	15/28 (57%)	1/28 (3.6%)	Recurrent infection	1/1 (100%) ****	No statistically significant difference in re-operation rates between UPC and non-UPC patients.

UPC, unexpected positive culture
* Only *C. acnes* cultures were studied.
** Only *Cutibacterium* were studied.
***This study is an addition of 137 cases to the cases already described in Pottinger et al. (6).
****Only 1/6 cultures for this patient grew *C. acnes*

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QUESTION 3: What is the treatment (if any) for unexpected positive cultures (UPC) in revision shoulder arthroplasty without clinical or radiographic signs of infection?

RECOMMENDATION: Unknown. Few publications offer protocols for addressing unexpected positive cultures. Of these, the most common options include antibiotics, re-operation and withholding any treatment. The lack of comparative data on outcomes of these therapy regimens makes it difficult to conclusively determine optimal management.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 100%, Disagree: 0%, Abstain: 0% (Unanimous, Strongest Consensus)

RATIONALE

A comprehensive literature review was performed to identify all studies on unexpected positive cultures (UPC) in shoulders undergoing revision arthroplasty. Searches for the terms "unexpected," "infection," "positive culture," "indolent infection," "gram-positive bacterial infections," "prosthesis-related infections" and "shoulder joint," "shoulder," "arthroplasty," "total joint," "replacement," "periprosthetic," "peri-implant," "shoulder prosthesis" were performed using the search engines PubMed, Embase and Scopus. These searches were conducted in February 2, 2018 and include results published through that time. Inclusion criteria included patients undergoing revision shoulder arthroplasty, with no clinical or radiographic signs of infection, who had positive cultures taken from the shoulder undergoing the revision. Only studies that focused on the potential treatment of these UPCs were included. Only English-language studies that presented original data on more than five patients meeting inclusion criteria were included. For articles with both unexpected positive cultures and known septic revisions, the patients with UPC were included in the review if the data was reported such that the patients meeting inclusion criteria could be separated. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria were followed. Eight articles met inclusion and exclusion criteria.

Of the eight studies [1–8] returned that allude to treatment of UPCs, only six described their treatment protocol, but these do not allow for definitive conclusions to be drawn regarding the effect of each treatment type on outcomes, if any were reported (see Table 1) [1–6]. Despite neither providing a methodology for treatment assignment, nor results that were not in aggregate, Foruria et al. [3] noted that their duration of antibiotic treatment (range: 8-700 days) was not associated with the likelihood of a second positive culture during follow-up [3]. In the study by Hsu et al. [5], a more standardized treatment protocol was developed and applied to their sample of 55 patients. However, this study was limited by the use of a control cohort (that received a different treatment course) that may have had a single positive culture, thus making it challenging to answer the question of the best treatment for UPCs using these data. These investigators found that three patients in both the culture-positive cohort (defined as at least two UPC, n = 27) and the control cohort (zero or one UPC, n = 28) required a subsequent procedure. None of these three culture-positive cohort patients, who received the extended antibiotic regimen, had subsequent positive cultures at their revision, while one of three control cohort patients did [5]. Two studies do present this data, but it is not robust [7,8]. Few studies fully meet the defined inclusion and exclusion criteria, and many of these report results in an aggregate. Only two studies compare different treatment options using non-aggregated outcomes.

Padegimas et al. [7] compared individuals undergoing shoulder arthroplasty revision, 28 of which had UPC and 89 who did not. They noted that all patients received the authors' standard, postoperative empirical oral antibiotics for two weeks and then may continue to receive antibiotics for an additional six weeks depending on culture results, presentation and intraoperative findings. One of the 10 patients who did not receive the additional 6-week regimen had reinfection. Of note though, there were three other patients who did not have UPCs who developed reinfection as well. A higher percentage of UPC patients underwent reoperation (20.2%) than those without UPC (7.1%), but this difference did not reach statistical significance ($p = 0.109$) [7].

In the study by Piggot et al. [8], 8 shoulders of the 24 with positive *C. acnes* cultures that they studied were "unexpected" as defined by our inclusion criteria. The primary outcome used in this study was termed "a favorable clinical outcome," which was defined as a post-treatment improvement in pain and function and a lack of additional operations. This metric was assessed at the latest possible clinical visit. Four of these eight UPC patients met the favorable clinical outcome endpoint; three did not, and one was lost to follow-up. The antibiotics that each of these eight patients received varied by clinical judgment and susceptibility