the Fungitell® Bulletin
volume 8, issue 3

Topic:

MEDICAL PROCEDURE-RELATED (1→3)-β-GLUCAN FALSE POSITIVES

SURGERY-ASSOCIATED (1→3)-β-GLUCAN FALSE POSITIVES DERIVED FROM GAUZE AND SURGICAL SPONGES

Fungitell® Bulletins are intended as technical advisory communications and as such are disseminated to the general public in order to highlight the significance of (1→3)-β-D-Glucan on human health. These communications do not promote a specific drug, therapy nor make any representation or suggestion concerning the suitability or effectiveness of a particular drug or therapy in patients harboring (1→3)-β-D-Glucan. Fungitell® is an adjunct diagnostic assay to be utilized in conjunction with clinical signs and symptoms for the diagnosis of invasive fungal infection. Fungitell® is currently 510(k) cleared for the detection and quantification of (1→3)-β-D-Glucan in human serum and should be used and interpreted only in a manner consistent with the current Instructions for Use.

Discussion:

The interpretation of serum (1→3)-β-glucan (BDG) titer results requires a complete understanding of the patient context. This includes the underlying conditions, co-morbidities, and potential exposure to medical treatments and materials that could contribute contaminating BDG to the patient. Past Fungitell Bulletins have reviewed various co-morbidities and medical infusions. This bulletin will address the role of surgical materials in the introduction of BDG to patients.

The principal surgery-associated contributors to patient contamination are surgical gauze and sponges.[1,2] These are composed of plant-derived material which contains BDG as a minor component and is termed callose in the plant sciences literature.[3,4,5] In plants, BDG is found in vasculature, plasmodesmata, wound response tissue, and pollen surface layers.[6] The manufacture of surgical gauze and sponges results in material which is rich in leachable BDG. Table 1 presents data on the levels of water-leachable BDG derived from a variety of sponges, gauze, and dressings.[7] Table 2 presents time course data for leached BDG from a surgical sponge.[7] Similar data as well as a time-course of leaching from a variety of surgical gauze materials was described by Kanamori et al (2009).[1] The intra-operative introduction of these materials to surgical fields, as well as their use in autologous blood recovery procedures, presents the opportunity for delivering a massive bolus of BDG to patients. The effect of iatrogenic patient contamination with BDG can result in the degradation of diagnostic specificity for invasive fungal disease. Specificity is affected by the length of time post-surgery that blood draws for BDG determination are taken. This was observed by Mohr *et. al.,* 2011 who observed that BDG specificity for IFD increased over a three day post-surgical period as clearance of the introduced BDG proceeded.[8] A recent case report describing the effects upon serum BDG titer after coronary artery bypass graft surgery with surgical sponge-based autologous blood recovery was described by Stycyznski et al (2018).[9] Patient serum BDG titer post-surgery was greater than 500 pg/ml, but no invasive fungal disease was established. Analysis of the leachable BDG from the surgical sponges and gauze used in the surgery revealed very high levels, in the multi-microgram/ml range. Serum BDG levels were 271 pg/ml on post-op Day 13 and undetectable at post-op day 52. In some specific types of surgery, such as liver transplant, BDG titer interpretation may be further complicated by deficiency in

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hepatic function, as hepatic clearance is the predominant pathway for BDG removal from the circulation.[10] Liver function (PELD scores [Pediatric End Stage Liver Disease]) has been experimentally correlated with serum BDG titer.[11,12]

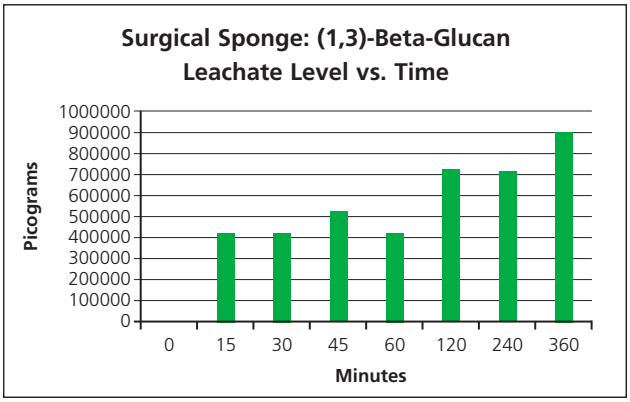
Accordingly, while the Negative Predictive Value of BDG titer is nearly universally observed to be very high, positive values require consideration of clinical context, co-morbidities, and potential sources of iatrogenic contamination. Serum BDG titers immediately post-surgery may reflect patient contamination. Longitudinal post-surgical BDG surveillance with rapidly declining titers may indicate clearance of surgical material-contributed BDG.

Table 1.

Glucan Leaching From Medical Cotton Products

	Mass of Product (gm)	pg Glucan/device
Manufacturer 1		
Sponge - 8 ply	1.56	1,534,799
Sponge - 12 ply	2.39	2,078,291
Sponge - Super	3.95	6,354,009
Abdominal Pad	2.39	2,912,308
Manufacturer 2		
Burn Dressing	33	9,393,278
Manufacturer 3		
Surgical Pad	2.1	3,206,817
Manufacturer 4		
Alcohol Swab	0.6	177,757

Table 2.



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