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Selective versus routine patch metal allergy testing to select bar material for the Nuss procedure in 932 patients over 10 years



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ABSTRACT

Aim of the study: The aim of the study was to determine the role of patch metal allergy testing to select bar material for the Nuss procedure.

Methods: An IRB-approved (11-04-WC-0098) single institution retrospective, cohort study comparing selective versus routine patch metal allergy testing to select stainless steel or titanium bars for Nuss repair was performed. In Cohort A (9/2004–1/2011), selective patch testing was performed based on clinical risk factors. In Cohort B (2/2011–9/2014), all patients were patch tested. The cohorts were compared for incidence of bar allergy and resultant premature bar loss. Risk factors for stainless steel allergy or positive patch test were evaluated. Main results: Cohort A had 628 patients with 63 (10.0%) selected for patch testing, while all 304 patients in Cohort B were tested. Over 10 years, 15 (1.8%) of the 842 stainless steel Nuss repairs resulted in a bar allergy, and 5 had a negative preoperative patch test. The incidence of stainless steel bar allergy (1.8% vs 1.7%, p = 0.57) and resultant bar loss (0.5% vs 1.3%, p = 0.23) was not statistically different between cohorts. An allergic reaction to a stainless steel bar or a positive patch test was more common in females (OR = 2.3, p < 0.001) and patients with a personal (OR = 24.8, p < 0.001) or family history (OR = 3.1, p < 0.001) of metal sensitivity.

Conclusion: Stainless steel bar allergies occur at a low incidence with either routine or selective patch metal allergy testing. If selective testing is performed, it is advisable in females and patients with a personal or family history of metal sensitivity. A negative preoperative patch metal allergy test does not preclude the possibility of a postoperative stainless steel bar allergy.

Level of evidence: Level III Treatment Study and Study of Diagnostic Test.

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The Nuss procedure is performed with either stainless steel or titanium bars that are alloys of various elements [1]. (Table 1). Allergies to the elements in stainless steel, especially nickel, have a reported prevalence of 10–15% in the general population [2,3]. A preoperative metal allergy test (PMAT) is a dermally applied test performed in some centers to screen for a stainless steel allergy. A PMAT can be performed with individual topical elements but the majority are performed with commercially available products (e.g., T.R.U.E.™ (Thin-layer Rapid Use Epicutaneous patch), AllergEAZE™) that screen for multiple elements in the stainless steel bar (SSB) [4-6]. Positive results necessitate the use of the alternative titanium bar for Nuss repair. While the routine use of titanium bars for Nuss repair would decrease the incidence of bar allergies, there are several disadvantages associated with its use including a substantial cost increase [1].

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Our initial screening strategy to evaluate for a potential SSB allergy required PMAT in a select group of patients considered to be at risk based on clinical variables. All other patients had stainless steel bars placed without testing. Using this strategy several patients repaired with stainless steel bars developed an allergy, therefore routine PMAT testing was recommended as a strategy to prevent this adverse outcome [7]. This study aims to compare the outcomes of selective versus routine metal allergy testing and identify clinical risk factors predictive of a stainless steel bar allergy.

1. Methods

An IRB-approved, single institution, retrospective cohort study comparing selective and routine patch metal allergy testing of 932 patients undergoing primary Nuss repair over a 10-year period (9/2004-9/2014) was performed.

Cohort A (9/2004–1/2011), PMAT was performed selectively on patients who reported a personal history or first-degree family history

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Table 1Components of stainless steel and titanium bars (Biomettm).

Stainless steel bar		Titanium bar	
Inorganic element	% Composition	Inorganic element	% composition
Chromium (Cr)	17–19	Aluminum (Al)	5.5-6.75
Nickel (Ni)	13-15	Vanadium (V)	3.5-4.5
Molybdenum (Mo)	2.25-3.0	Iron (Fe)	0.3
Manganese (Mn)	2	Yttrium (Y)	0.005
Copper (Cu)	0.5	Titanium (Ti)	Balance
Trace	0-0.3		
Iron (Fe)	Balance		

of metal sensitivity and those with multiple food, drug, or environmental allergies. Patients without these clinical risk factors had stainless steel bars placed without a PMAT. A small number of patients had titanium bars placed without a PMAT. These patients were excluded from the statistical analysis since their true stainless steel allergy status could not be confirmed.

Cohort B (2/2011–9/2014), all patients underwent PMAT. Patients with a positive test received titanium bars and patients with a negative test received stainless steel bars. Only patients that underwent primary Nuss repair and completed therapy with bar removal were included in the study.

In order for a patient to be categorized as having a SSB allergy in this study the patient either had to have a positive PMAT at any time or allergic symptoms after stainless steel bar placement that improved with steroids or bar removal. The cohorts were compared for the incidence of bar allergies and resultant premature bar loss. In addition, demographic risk factors for a reaction to the elements of stainless steel in a dermal patch test or a stainless steel bar allergy were examined. One-tailed Fisher's exact test was used to analyze statistical significance of categorical variables. chi-Square test and logistic

regression were used to produce odds ratios in the statistical analysis of risk factors.

2. Results

In cohort A, 63 (10.0%) of the 628 patients were selected for a PMAT based on clinical risk factors. Only one of the 37 patients with a negative PMAT developed a SSB allergy. There were 565 patients in this cohort that did not have a PMAT and underwent Nuss repair with a SSB (Fig. 1). Ten (1.8%) of these patients developed a SSB allergy (Table 2). In cohort B, all 304 patients had a PMAT and 64 (21.1%) tested positive requiring a titanium bar repair. The remaining 240 patients had a negative PMAT and underwent repair with a SSB (Fig. 2). Four (1.7%) of these patients developed a SSB allergy. (Table 2)

Over 10 years, 90 patients had titanium bars placed with no allergic events, while 842 patients had stainless steel bars placed with 15 (1.8%) developing a bar allergy. Notably, 5 of the 15 patients that developed a SSB allergy had a negative PMAT (Figs. 1 and 2). The incidence of a stainless steel bar allergy (1.8% vs 1.7%, p=0.57) and resultant premature bar loss (0.5% vs 1.3%, p=0.23) was not statistically different between cohorts. Only 6 (0.7%) of the 842 stainless steel bars placed over 10 years required premature bar removal due to a bar allergy (Table 3).

The mean time for symptoms of a SSB allergy to be recognized was 22 weeks (range 2–52 weeks). Pain (73%), peri-incisional erythema (60%), persistent lethargy (33%), and shortness of breath (33%) were the most common symptoms. Bar preservation was achieved in 9 (69%) of the 13 patients who agreed to undergo steroid therapy (Table 2). Nickel was the most common cause for a SSB allergy in our series (80%) and the most common allergen detected by dermal patch testing (61%), but other elements were also associated with SSB allergies (Table 4).

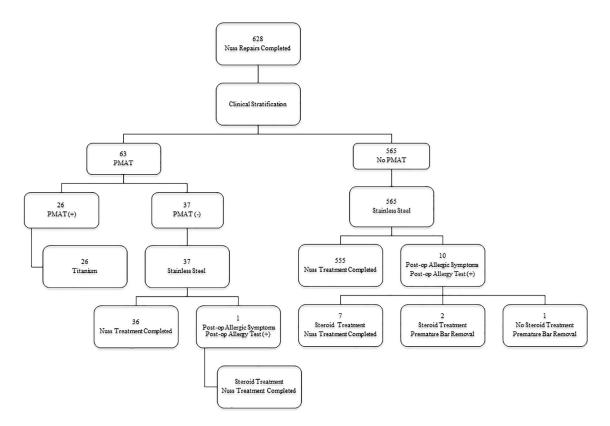


Fig. 1. Cohort A: Selective Metal Allergy Testing (9/2004–1/2011). PMAT = Pre-operative Metal Allergy Test.

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