



# The effect of lipid levels on patient-reported outcomes in patients with rotator cuff tears

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**Background:** Lipid disorders could be associated with the prevalence and outcomes of rotator cuff diseases. This study aimed to learn how levels of various types of lipids influence the patient-reported outcomes of patients with rotator cuff tears (RCTs).

**Methods:** Data from a cohort study of 135 patients with RCTs were used. The outcome measures included Western Ontario Rotator Cuff (WORC) index, American Shoulder and Elbow Surgeons (ASES) standardized shoulder assessment form, Single Assessment Numeric Evaluation, visual analog scale for pain and satisfaction, and Veterans RAND 12-Item Health Survey (VR-12). Multivariable random-effects models were built to examine how total cholesterol, triglycerides, high-density lipoprotein (HDL), low-density lipoprotein, and ratio of total cholesterol to HDL influence each outcome, controlling for covariates.

**Results:** After adjusting for age, gender, surgery, smoking, and baseline outcome values, patients with triglycerides >150 mg/dL had significantly higher pain visual analog scale ( $\beta = 5.86$ ;  $P = .017$ ) and lower VR-12 physical component summary ( $\beta = -2.71$ ;  $P = .002$ ) scores. Patients with low HDL had significantly worse WORC ( $\beta = 132.26$ ;  $P = .020$ ) and ASES ( $\beta = -7.05$ ;  $P = .005$ ) scores, more pain ( $\beta = 6.69$ ;  $P = .024$ ), and less satisfaction ( $\beta = -6.53$ ;  $P = .008$ ). The ratio of total cholesterol to HDL was associated with worse WORC ( $\beta = 58.46$ ;  $P = .006$ ) and ASES scores ( $\beta = -2.74$ ;  $P = .002$ ), more pain ( $\beta = 4.49$ ;  $P < .001$ ), and worse VR-12 physical component summary score ( $\beta = -1.03$ ;  $P = .017$ ).

**Conclusions:** Dyslipidemia may decrease the improvement of patient-reported outcomes in patients undergoing treatment for RCTs; high triglycerides and low HDL may have the most impact.

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Rotator cuff diseases are of great concern in the musculoskeletal area because of their high prevalence, with an overall prevalence of >50% among patients older than 80 years.<sup>8,22</sup> Rotator cuff tears (RCTs) have been proved to lower patients' quality of life by causing pain, weakness, and loss of shoulder range of motion.<sup>17</sup> Therefore, it is necessary for researchers to look into the risk factors of RCTs and to study how they influence patient-reported outcomes.

The pathogenesis of RCTs remains unknown.<sup>20</sup> Extrinsic and intrinsic theories have been developed to explain RCTs.<sup>11</sup> The major extrinsic factor is shoulder impingement. The intrinsic mechanisms, however, are more complicated. Degeneration, inflammation, oxidative stress, and hypovascularity are all thought to be intrinsically related to RCTs, and lipid disorders may play an important role in some of these conditions.<sup>22</sup> Most of the lipids in the tendons

have been shown to be derived from the lipids in circulation.<sup>24</sup> Several studies have associated hyperlipidemia with a range of musculoskeletal manifestations, including tendon xanthomas, tendo Achillis tendinitis, transient tendo Achillis pain, migratory polyarthritides, and oligoarthritis.<sup>13</sup> In a mouse model, Beason et al<sup>5</sup> showed that hypercholesterolemia could reduce the tendon elastic modulus and may have a detrimental effect on overall tendon properties.

Several studies have investigated the relationship between dyslipidemia and rotator cuff diseases, finding that hyperlipidemia is an independent risk factor for the development of rotator cuff disease and that patients with dyslipidemia had a higher prevalence of RCTs.<sup>10,14</sup> More specifically, total cholesterol, triglycerides, and low-density lipoprotein (LDL) cholesterol were found to be positively associated with RCTs, whereas high-density lipoprotein (HDL) cholesterol was inversely related to tears.<sup>1</sup> With regard to patient-reported outcomes, it has been found that among patients diagnosed with supraspinatus tendinopathy, the pain decreased significantly less after nonsurgical treatment in the hyperlipidemia group than in the nonhyperlipidemia group.<sup>12</sup> To the authors' knowledge, no cohort study has been done to study the effects of specific lipid concentrations on the outcomes of RCTs.

This study was approved by the University of Michigan Institutional Review Board: HUM00056320.

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This study aimed to learn how levels of various types of lipids may influence the patient-reported outcomes of patients with RCTs. We hypothesized that dyslipidemia, which includes higher total cholesterol, triglycerides, and LDL or lower HDL, had a detrimental effect on the improvement of the designed outcome measures.

## Methods

The project used data collected during a prospective cohort study supplemented by a chart review of included patients. The choice of intervention (surgical vs. nonsurgical) was determined by the patient and physician as a part of standard clinical practice. Given that these patients all had RCTs, surgery repair was done or the patients received physical therapy. Patients with potential RCTs were identified by attending clinicians from March 26, 2012, to March 3, 2015. Inclusion criteria were age 18 years or older, full-thickness RCT of any size or location as diagnosed by magnetic resonance imaging or diagnostic musculoskeletal ultrasound, unilateral tear, first tear of the affected shoulder, and nonoperative treatment for <4 weeks. Exclusion criteria were a RCT in which complete footprint coverage was not possible; any history of prior surgery, fracture, dislocation, or infection of the affected shoulder; inflammatory joint disease of the affected shoulder, including rheumatoid arthritis; and an open repair, including the subscapularis.

### Data collection

All demographic information was collected at baseline, including age, gender, weight, height, workers' compensation (yes/no), comorbidities, shoulder range of motion, tear size, location, days since injury, cause of injury, and medical history. Outcome measurements were collected at baseline and 4, 8, 16, 32, 48, and 64 weeks by e-mail. Lipid profiles were obtained from patients' electronic health records.

### Exposure and covariates

The major exposure variables in this study, the lipid profiles, were continuous variables. We also dichotomized the variables on the basis of standards of the National Heart, Lung, and Blood Institute<sup>19</sup> for the borderline high and high total cholesterol level ( $\geq 200$  mg/dL), borderline high and high LDL cholesterol level ( $\geq 130$  mg/dL), low HDL cholesterol level ( $< 40$  mg/dL), and borderline high and high triglyceride level ( $\geq 150$  mg/dL).

Other covariates in the analysis included age, gender, smoking, and surgery, which were collected at baseline.

### Outcomes

A variety of tools were used to measure the outcomes of RCTs, including functional outcomes, psychological conditions, and pain. The primary outcome was the Western Ontario Rotator Cuff (WORC) index, which is a self-reported instrument to assess the quality of life of patients with rotator cuff disease.<sup>16</sup> Secondary outcomes included the American Shoulder and Elbow Surgeons (ASES) standardized shoulder assessment form, Single Assessment Numeric Evaluation (SANE), visual analog scale (VAS) for pain, VAS for satisfaction, and Veterans RAND 12-Item Health Survey (VR-12).

#### WORC index

The WORC is commonly used to evaluate the patient's quality of life. This scale consists of 21 items focusing on 5 domains: physical symptoms, sports/recreation, work, lifestyle, and emotions. Each item has a score range of 0–100, with a possible total score sum of 0–2100. Higher scores correspond to lower quality of life.<sup>16</sup>

#### ASES standardized shoulder assessment form

The ASES assesses patients with shoulder diseases through both self-reporting and medical professionals' evaluations. The self-report consists of 2 sections: pain (1 question) and activities of daily living (10 questions). Each section weights equally, and all sections combined form a total score of 0–100.<sup>18</sup>

#### SANE

The SANE rating is determined by the patient's written response to only 1 question: How would you rate your shoulder today as a percentage of normal (0%–100% scale, with 100% being normal)? Patients are instructed to provide SANE ratings in whole numbers.<sup>25</sup>

#### Pain and satisfaction VAS

A VAS is usually a 100-mm horizontal line to measure a characteristic or attitude that is believed to range across a continuum of values. The patient marks the line at the point that best represents the patient's perception of current state.<sup>9</sup> This study used VAS for pain (from no pain to worst possible pain) and satisfaction (from least satisfied to most satisfied) separately, both ranging from 0 to 100 points.

#### VR-12

The VR-12 is a self-reported health survey used to measure health-related quality of life and disease burden. The 12 items in the survey indicate the following 8 domains: general health perceptions, physical functioning, role limitations due to physical or emotional problems, bodily pain, energy fatigue, social functioning, and mental health. Two scores are derived from the 12 items; one mainly focuses on physical health (physical component summary [PCS]), and the other mainly focuses on mental health (mental component summary [MCS]), with lower scores indicating worse conditions.<sup>23</sup>

#### Statistical analysis

SAS 9.4 (SAS Institute, Cary, NC, USA) was used in all statistical analyses. Demographic, surgical, and comorbidity characteristics and baseline outcome values were compared between our target population, who had lipid profiles in their electronic health records, and those without lipid profiles. The *t*-test and Wilcoxon rank sum test (if variables are or are not normally distributed, respectively) were used to compare continuous variables (age and all the baseline outcome values) between the 2 groups of patients, and  $\chi^2$  test was used to compare categorical and binary variables (gender, having surgery or not, smoking or not; Table I).

The mean value of each specific lipid and also the percentage of high total cholesterol, high triglycerides, high LDL, and low HDL were summarized (Table II). To determine the overall trend of each outcome, we also plotted the means of the outcomes by each lipid group during the 64-week period.

To explore the potential true effects of lipids on longitudinal outcomes and the influence of covariates, we used multivariable random-effects models, setting each outcome measure as the response variable, each binary lipid variable as exposure, and adjusting for age, gender, surgery, smoking, week since baseline, and corresponding baseline outcome values. Multiple imputation (10 data sets for each model) was used to replace missing outcome data, which is a statistical technique to analyze incomplete data sets. The effects are summarized in Table III using beta estimates with 95% confidence intervals. Statistical significance was defined as *P* value < .05.

## Results

The cohort included 222 patients, of whom 135 patients had lipid profiles and were included in this analysis. In comparing those with

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