Varithena®
(polidocanol injectable foam) 1%

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Evaluating patient preferences for thermal ablation versus nonthermal, nontumescent varicose vein treatments

Objectives

To measure patient preferences for attributes associated with nonthermal, nontumescent (NTNT) and thermal ablation (TA) varicose vein treatments

- Leverage a choice-based conjoint model to determine which attributes impact a patient's choice for treatment and the resulting preferred endovenous therapy, assuming equal cost and unrestricted choice
- Determine relative importance of each attribute in the treatment decision
- Understand the trade-offs a patient would be willing to make because of the desired attributes

Patients

(n= 70; three centers, choice-based conjoint, observational)

- Patients currently eligible for treatment or currently being treated were included in the study
  - 56% were at the beginning of treatment, 13% mid-treatment, and 31% near the end of treatment
  - 70% female; 30% male
  - 41% had a household income of <$60,000

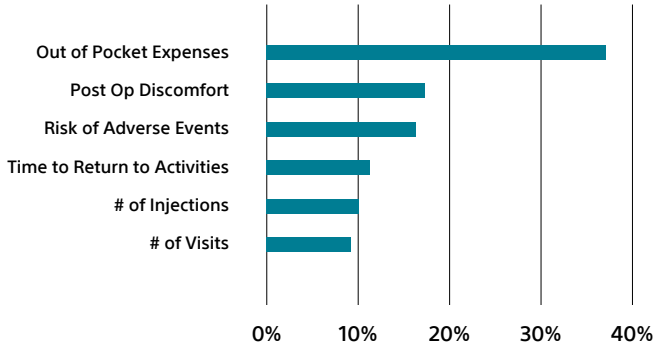
Methods

- Each participant received a random version of the survey delivered in person by a study author
- Patient preference was measured for three treatment options: NTNT, TA, or none (to represent compression, weight loss or exercise)
- Active treatment modalities (NTNT and TA) were categorized in the following six attributes:
  1. Number of injections: 1-3 (NTNT) or 4-7 (TA)
  2. Number of visits: 3-5 (NTNT) or 4-7 (TA)
  3. Postoperative pain: barely noticeable (NTNT) or noticeable (TA)
  4. Risk of an adverse event: 8 in 200 (NTNT) or 1 in 200 (TA)
  5. Time to return to normal activities: 1-2d (NTNT) or 3-5d (TA)
  6. Out-of-pocket expenses ($0, $50 or $150)
- Patients were shown ten screens on an iPad that each displayed three hypothetical treatment scenarios for the six attributes – patients did not know the treatment type that was associated
- Patients would then choose one of the available treatment scenarios or none of the above
- Using regression coefficients, investigators estimated willingness-to-pay measures, tradeoff values, and overall value of various attribute combinations based on the treatment selections made
- A market simulation was performed to compare clusters of attributes that mimic NTNT and TA treatments to predict market choice and understand attribute preferences

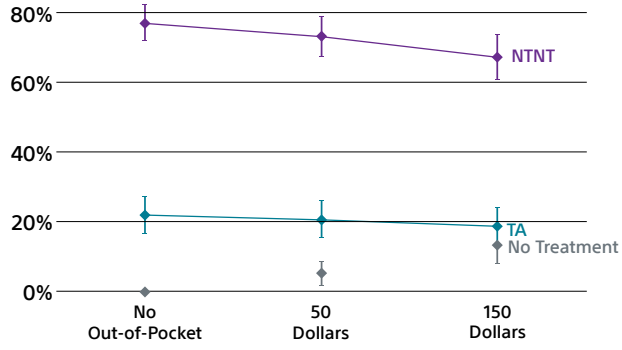
Key Results

- 60–80% of respondents favored attribute combinations that correspond to NTNT procedures over TA regardless of the level of out of pocket spending
  - 14% would forgo treatment with a $150 copay while 6% would forgo treatment with a $50 copay
- The analysis indicates high sensitivity to out of pocket costs for minimally invasive varicose vein treatment and relatively high willingness to pay for reduction in adverse events, postoperative pain, the number of injections, fewer visits and faster return to normal activity
- A few differences were noted by demographics, with males willing to pay more for fewer injections per visit, reduced postoperative discomfort and faster return to normal activity
- Patients with an income of <$60,000 were highly influenced by cost with relative importance of over 50%

Relative Importance of Each Attribute



Overall Market Preference



Limitations

- The study was conducted at three locations in New Jersey; results may be regionally specific
- Scores are sensitive to the levels chosen in the survey design:
  - Choosing $100 vs $200 instead of $1 vs $100 could impact results
  - A pilot was conducted to inform survey choices

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Varithena (polidocanol injectable foam)
INDICATIONS Varithena (polidocanol injectable foam) is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

IMPORTANT SAFETY INFORMATION The use of Varithena is contraindicated in patients with known allergy to polidocanol and those with acute thromboembolic disease. Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately. Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease may be at increased risk for tissue ischemia. If intra- arterial injection of polidocanol occurs, consult a vascular surgeon immediately. Varithena can cause venous thrombosis. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis. The most common adverse events observed were pain/discomfort in extremity, retained coagulum, injection site hematoma or pain, common femoral vein thrombus extension, superficial thrombophlebitis, and deep vein thrombosis. Physicians administering Varithena must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease and be trained in the administration of Varithena.

For Full Prescribing Information visit Varithena.com

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