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FEASIBILITY STUDY FOR EVALUATING LEVATOR ANI TEAR STATUS AFTER SECOND VAGINAL DELIVERY

Hypothesis / aims of study

A parent study of women recruited immediately after their first childbirth was conducted to determine status of the levator ani muscle by magnetic resonance imaging (MRI). All women recruited had obstetric risk factors for injury on first birth (e.g. forceps delivery, 3rd or 4th degree tear, maternal age great than 35 years, second stage of labor longer than 150 minutes). To pilot the possibility of longer-term follow-up, the opportunity was offered for these same women to continue being assessed after their second birth. The long-term goal is to test if LA status changes over time and deliveries. The short-term goal is to establish feasibility of long term follow-up and pilot data needed to perform power analysis for sample size calculation.

Study design, materials and methods

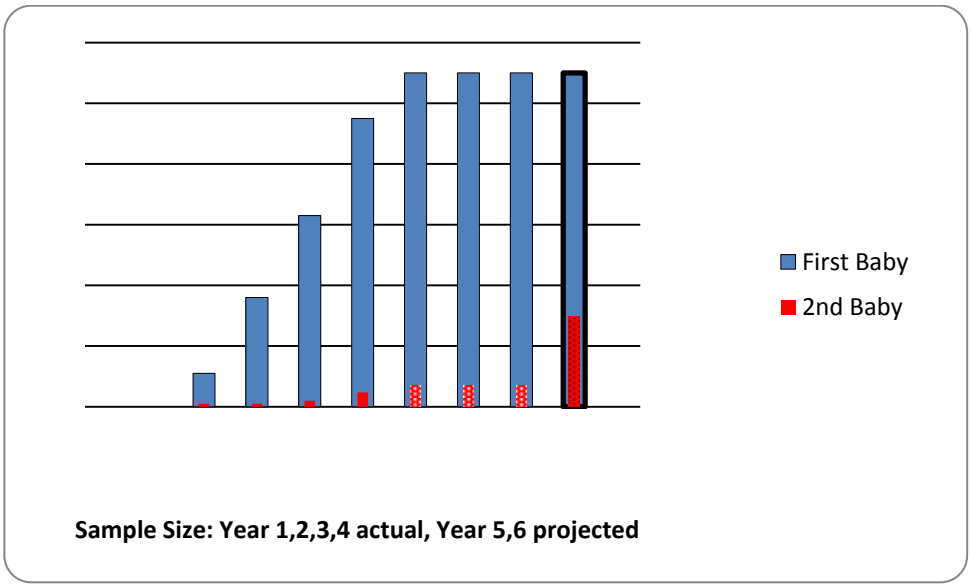
At the mid-way point of the parent study, recruitment projections are expected to be 110 women. Parent study woman are consented, agree to contact the project staff should they become pregnant with a second child and desire follow-up after their second birth. Per parent study protocol, women receive pelvic MRI approximately 6 weeks and 7 months following their first birth. In the pilot follow-up study, women receive an additional MRI after their second birth (timeframe between 6 weeks to 2 years following second delivery.)

Documentation for feasibility for following a larger sample size into second birth would be determined at end of year 4, so as to obtain additional funds in timely fashion for following 2nd birth women in years 5-7. Year 5-7 recruitment projections are roughly estimated from patterns observed in years 1-4. Assumptions for projections are: 1) First birth recruitment would end mid-5th year of parent project, and 2) Percentage of women becoming pregnant with second child would peak in the fifth year of parent study and stay stable across the next three years. Based on these assumptions, total number of women expected to have a post-second birth MRI by end of study year seven was estimated by findings through end of year four.

MRI results of the initial five women studied after second birth were used to estimate effect size of second birth on levator ani status, including stratification by levator ani status after first birth.

Results

The figure shows projected estimates that a total of 30 women can be expected to complete MRI after their second births by end of study year seven, assuming a total of 110 recruited into the parent study. The projection is based on the 95 women recruited over the first four years of the parent study, nine reporting second pregnancies to the study coordinator. Five have delivered and had the post second birth MRI.



Sample Size: Year 1,2,3,4 actual, Year 5,6 projected

Of the five women, three were known to have partial levator ani tear after first birth. For the three the partial tears extended to complete tears on at least one side of their levator ani muscle after the second birth. The remaining two women had no levator ani tear after first birth, and retained intact levator ani status after second birth.

Interpretation of results

A power analysis was conducted for sample size calculation for hypothesis testing. There are two groups. Group 1 with known levator tears entering 2nd birth and Group 2 with levator muscles intact entering second birth. Using the data from our five pilot women, a conservative estimate is 70% of Group 1 will show a complete levator tear on at least one side after second birth; only 10% of Group 2 will show a complete levator tear. With 80% power, a sample size of approximately 25 women is required to test the hypothesis of significant difference between groups in complete levator tears after second vaginal birth.

Concluding message

This pilot study concludes it is feasible to longitudinally study childbearing age women with serial pelvic MRI to document levator ani status changes after first and second vaginal birth. Adequate sample size for hypothesis testing was also established.

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Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Michigan Medical School Institutional Review Board for Human Subject Research (IRBMED)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**