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The postural response of the pelvic floor muscles during limb movements: a methodological electromyography study in parous women without lumbopelvic pain

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Abstract

Background: Pregnancy-related lumbopelvic pain is common. More than 30% of women have persistent pain 3 months after giving birth. There is no consensus regarding the pathology. However, coordination of muscle activity by appropriate timing and amplitude is necessary for maintaining adequate stability in the lumbopelvic area. The aim was to develop a method using surface electromyography to detect a feed-forward response in the pelvic floor muscles during limb movements performed at a comfortable speed applicable in future studies for women with lumbopelvic pain.

Methods: Ten parous women with no lumbopelvic pain in the past 12 months were included. Surface electromyographic activity was recorded from the pelvic floor muscles and unilaterally from transverses abdominis/internal oblique, rectus abdominis, erector spinae, hip adductors, rectus femoris and deltoïd. The subjects performed leg lift in supine and arm lift from standing. The electromyographic onset was related to the initiation of the movement.

Findings: In the majority of the women the electromyographic onsets of the pelvic floor muscles occurred before the movement was initiated, regardless of whether it was a leg or an arm lift. In addition, electromyographic onsets for the other muscles, except the rectus abdominis during the arm lift, also occurred prior to the movements.

Interpretation: The findings suggest a feed-forward response in the pelvic floor muscles during leg and arm lifts in women who had previously given birth and were without lumbopelvic pain. Movements performed at a comfortable speed seem to be useful in order to detect such a response.

Keywords: low back stability; feed-forward; abdominal muscles; temporal parameters
1. Introduction

Pregnancy-related lumbopelvic pain is common. In early pregnancy (gestation week 12–18), 62% of women were classified to have lumbopelvic pain and 33% had persistent pain 3 months after giving birth (Gutke et al., 2008). In a long-term follow-up 16% of the women who had suffered from pregnancy-related lumbopelvic pain reported persistent pain 6 years after childbirth (Ostgaard et al., 1997).

Recent research has focused on the importance of muscle activation for motor control and stability of the lumbopelvic region (Hungerford et al., 2003; Vleeming et al., 1997). The muscles surrounding the abdominal cavity have been found to play an important role for controlling the spine stability (Cresswell et al., 1994; Hodges and Gandevia, 2000; Hodges and Richardson, 1996, 1997a).

Joint stability has been proven to be dependent of a feedforward manner, i.e. electromyographic (EMG) onset before movement or perturbation. A pre-activation of the transversus abdominis muscle and the internal oblique muscle, as well as an increased intra-abdominal pressure prior to an expected perturbation, have been observed, which indicates a feed-forward postural strategy designed to increase the stability of the spine (Cresswell et al., 1994). The same feed-forward regulation has been demonstrated in the deep abdominal muscles (Hodges and Richardson, 1996, 1997a,b; Marshall and Murphy, 2003) and the diaphragm (Hodges et al., 1997; Hodges and Gandevia, 2000) as a response to rapid single or repetitive arm movements as well as during standing hip movements (Hodges and Richardson, 1997c; Hungerford et al., 2003).
Less focus has been directed towards the feed-forward mechanism in the pelvic floor muscles (PFM). Altered motor control strategies of the PFM have been identified in subjects with pain over the sacroiliac joints during the active straight leg raise test (O’Sullivan et al., 2002). In addition, pelvic floor dysfunction, such as lower endurance in the PFM, has been demonstrated in patients with pregnancy-related low back pain (Pool-Goudzwaard et al., 2005). The PFM are a part of the surrounding muscles of the sacroiliac joints, and should therefore contribute to stabilize the sacroiliac joints as well as the spine (Snijders et al., 1993a,b). Altered motor control of the deep muscles including the PFM may be a reason for decreased lumbopelvic stability, resulting in pain. However, feedforward responses in the PFM should not occur only in response to a sudden rapid single movement or repetitive movements, but also to other types of external loadings, for example limb movements performed at various speeds.

EMG onset is one of the most common temporal parameters used to study appropriate timing of muscle activation during movements and postural loadings (Hodges and Bui, 1996). However, there is no standard method described in the literature for how to determine EMG onsets. Both visual (Hodges et al., 2007; Lee et al., 2009; Smith et al., 2007a) and computer-based methods (Hodges and Richardson, 1997b; Marshall and Murphy, 2003) are used. Hodges and Bui (1996) evaluated different combinations of computer-based parameters: (a) width of window of samples required to exceed threshold (ms), (b) the magnitude of the deviation from the baseline required to indicate the threshold (SD), and (c) low pass filter (Hz). They found that visually derived data did not differ significantly from the computer-based data when using appropriate combinations of the parameters. However, computer-based methods increase the objectivity of the analyses.
The aim of this study was to develop a method using surface EMG and a computer-based method to detect a feed-forward response in the PFM during leg lift in supine position and arm lift in standing position performed at a comfortable speed in women who previously had given birth and with no history of lumbopelvic pain in the previous 12 months.
2. Materials and methods

2.1. Subjects

Ten women volunteered to participate. Inclusion criteria were age between 20 and 40 years and previously given birth vaginally, but not in the last 12 months. Exclusion criteria were: ongoing pregnancy, recurrent lumbopelvic pain in the previous 12 months, diagnosed neurological or rheumatic disease, or fracture, operation or neoplasm in the femur, pelvis or spine or if they had undergone any gynaecological operations. The mean (SD) for age was 37 (3) years, body mass 61 (6) kg, height 167 (6) cm and body mass index 22 (3) kg/m². The number of pregnancies ranged from 1 to 3. Four women reported 1 or 2 on a 12-point severity scale for stress urinary incontinence which equals slight leakage (Sandvik et al., 1993; Sandvik et al., 2000). All ten women were able to contract their PFM voluntarily on verbal command during vaginal palpation. All women signed written informed consents prior to their participation in the study. The Ethics Committee of the Local University approved the project.

2.2. Electromyography

Periformᵀᴹ vaginal probe (Neen HealthCare, Dereham, UK) recorded the EMG activity of the PFM. The probe was 7.5 cm long, with a circumference of 10 cm and had monopolar configuration. There were two longitudinal recording plates (1.5 cm wide and 3.5 cm long) situated alongside the body of the probe (Voorhamvan der Zalm et al., 2006). The ICC(3,2) for the probe has been found to range between 0.81 and 0.96 within a single session and 0.54–0.89 between days (Brown and McLean, 2008). A ground electrode and an amplifier were placed on the right hip at the iliac crest in order to reduce noise from the recordings of the PFM.
EMG activity was also recorded unilaterally from the erector spinae muscle, ~3 cm lateral to the L1 spinous process, the hip adductors, ~¼ of the line between the groin and the knee, the rectus femoris muscle, ~½ of the line between spina iliaca anterior superior and the superior part of the patella, the anterior part of the deltoid muscle, ~2 cm distal and anterior of the acromion, the rectus abdominis muscle, ~2 cm lateral to the umbilicus and from the transversus abdominis/internal oblique muscle, ~2 cm medial of the spina iliaca anterior superior. Since our interest was to record EMG activity from the transversely oriented abdominal muscles, differentiation between the two muscles was not necessary. The muscles were located by palpation during submaximal isometric contraction and the electrodes were placed at the most prominent place of the muscle. The recording of the abdominal and the back muscles was made on the contralateral side with respect to the side performing the leg or arm lift and the recording of the leg and arm muscles was made on the ipsilateral side.

The EMG recordings were made with disposable pre-gelled silver/silver-chloride surface electrodes (Blue sensor, M-00-S, Medicotest, Denmark, diameter of active part 10 mm). Skin preparations were performed according to recommendations from Surface EMG for non Invasive assessment of muscles (SENIAM) (Hermens and Fredriks, 1997). The skin at each electrode site was prepared by first shaving and cleaning with 70% alcohol to facilitate electrode adherence and conduction of the EMG signals. Each pair of silver/silver-chloride surface electrodes was placed with 2 cm center-to-center distance. One ground electrode and amplifier were placed approximately 10 cm from each measuring area on the muscle. EMG activity was recorded in resting positions during 2 s, both in supine and standing and served as baseline when analysing EMG onsets. Two repetitions, 4–5 s, of maximal voluntary contractions (MVCs) were performed for each muscle.
Pelvic floor muscles (PFM): supine and standing position. Instruction: contract the PFM and lift the pelvic floor towards the abdominal cavity.

Transversus abdominis/internal oblique muscle: supine position with legs extended.
Instruction: tighten the lower abdomen by drawing the umbilicus against the back.

Rectus abdominis muscle: supine position with knees flexed approximately 90°, feet hip-width apart. Arms aligned next to the torso; the upper body restrained by a strap. Instruction: tighten the lower abdomen by drawing the umbilicus against the back and lift the upper body from the couch against the strap.

Erector spinae muscle: prone position with the arms next to the torso; the upper body restrained by a strap. Instruction: perform a back extension against the strap.

Hip adductor muscles: supine position with knees flexed approximately 90°, feet hip-width apart. Arms aligned next to the torso; the test leader fixated the pelvis on the contralateral side. Instruction: perform an adduction against the manual resistance placed on the inside of the knee by the test leader.

Rectus femoris muscle: supine position. The contralateral foot was placed on the couch, the ipsilateral knee was flexed approximately 30° and restrained by a strap. Instruction: perform a knee extension against the resistance.

Deltoid muscle: standing position. The elbow was flexed 90°, and the shoulder was abducted approximately 20°. Instruction: perform abduction against the resistance placed on the outside of the elbow by the test leader.

EMG signals were collected with 1000 Hz sampling frequency (bandwith = 8–500 Hz, CMRR = 110 dB, Input impedance = 10 Gohm, Gain: 305) by a ME6000 EMG eight-channel unit system (MEGA Electronics Ltd, Kuopio, Finland) using a 14-bits Analog to Digital
converter and Butterworth filter. The data were acquired and processed with MegaWin software, version 2.3.4 (MEGA Electronics Ltd, Kuopio, Finland).

2.3. Limb movements
Each movement was repeated five times with approximately 40-s rest period between each repetition. Each repetition was performed on verbal command. The women were instructed to perform the movements at a comfortable speed, i.e. the movement was performed at a self-paced speed.

(A) Leg lift: The women rested in a supine position on a couch with the lower limbs extended straight. Both arms were placed alongside the torso. The foot of the leg that performed the movement was placed on a switch that indicated the start of the lift. The women were instructed to lift the leg 20 cm above the couch with knee extended (i.e. active straight leg raise test). In addition, the leg lift was performed with a 2-kg weight fixed to the ankle. All muscles except the deltoid muscle and the erector spine muscle were recorded during the leg lifts.

(B) Arm lift: The women stood barefoot in a relaxed position with feet placed hip-width apart and one side of the body facing the couch. The elbow was flexed approximately 90°, and the antebrachium was placed on the switch. A 5-kg weight was fixed around the wrist, and the contralateral arm was held alongside the body. The women were instructed to lift the arm (i.e. shoulder flexion). They were allowed to extend the elbow while performing the shoulder flexion. All muscles except the rectus femoris muscle were recorded during the arm lift.

2.4 Signal processing and data analyses
The EMG amplitude was calculated as continuous root mean square (RMS) averaging using a moving window of 10 ms with MegaWin software. The highest window across all MVCs was
used to represent the maximal voluntary activation amplitude for each muscle. The peak value for each recorded muscle during the leg lifts and the arm lift was normalized to the peak values in the MVC for each muscle (i.e. relative value of one muscle = peak value during the limb movement/peak value during the MVC).

To study the EMG onset, continuous RMS averaging was first computed across each recording of the limb movement using a moving window of 1 ms and filtered at 50 Hz with MegaWin software. The EMG onsets were calculated using MATLAB version 7.1.0.246 (R14) Service Pack 3 (The MathWorks Inc., Natick, USA) based on an algorithm described by Hodges and Bui (1996). The EMG onset was defined as being the start of a 50 ms period where the activity exceeded the mean baseline activity by 2.5 SD. This algorithm was used for all muscles except for the rectus femoris muscle in which the EMG activity had to exceed 25 µV for a period of 50 ms to be accepted as an EMG onset. Unfortunately, increased background activity in the deltoid muscle during the arm lift made it impossible to analyse the EMG onset of the deltoid muscle. Each file processed in MATLAB was also checked visually to ensure that EMG onsets were not a result of obscured activity or misrepresented movement artefact or electrocardiogram (Hodges and Bui, 1996).

Disturbances from electrocardiogram could be detected visually in the raw data in the signals recorded from the torso. The electrocardiogram rhythm was therefore obtained by calculating the covariance function from the EMG signals using MATLAB. Obvious peaks appear in periodic signals at points corresponding with the electrocardiogram rhythm. The y-value of the point corresponding with the heart rhythm indicates the strength of the correlation between the points, and the x-value specifies the time between the points. The first point, from the covariance function, gives the interval between the heartbeats and it was used to
detect the heartbeats. However, as they do not necessarily occur at the same time intervals, the
algorithm was programmed to identify the point in an interval when a heartbeat should occur.
This point of interest was then replaced with the mean between the previous point and present
point.

EMG onsets that occurred ≥400 ms after the initiation of the movement were not defined as
onsets since a feed-forward response to the initiation of the movement should appear earlier.
If an EMG onset occurred more than 400 ms prior to the initiation of the limb movement, the
onset was defined as an increase in the background activity. Based on the PFM, the two most
extreme repetitions of the five were excluded. The remaining three repetitions were used to
analyse the EMG onsets and activation amplitudes for all muscles.
3. Results

All ten women performed the leg lift with no extra weight and the arm lift. After preliminary analyses of the recordings from the two first test sessions we chose to put a higher postural demand on the PFM during the leg lift to increase the external demand to get a more distinct EMG onset of the PFM. Therefore, the eight remaining women also performed the leg lift with an extra 2-kg weight strapped around the ankle.

3.1 Leg lifts

In median, the postural response for all muscles occurred before the initiation of the two types of leg lifts (Fig. 1). Two women had an increase in the background activity of the PFM during the two leg lifts and this made it difficult to detect EMG onsets and they had therefore to be excluded from further analyses.

The EMG onset of the PFM occurred before the start of the leg lift with no extra weight in six of the eight women but after the start in two women. In all six women, the EMG onset of the PFM could be demonstrated before the start of the leg lift with the extra 2-kg weight.

During the leg lift with no extra weight, one of the eight women lacked EMG onset of the transversus abdominis/internal oblique muscle and during the leg lift with the extra 2-kg weight, one of the six women lacked EMG onset of the rectus abdominis muscle.

The activation level of the PFM during the leg lift with no extra weight ranged between 13% and 71% with the median value 20% of the MVC (Fig. 2). During the leg lift with the extra 2-kg weight the activation level ranged between 14% and 125% with the median value 38% of the MVC (Fig. 2).
Fig. 1: The median, the 25th percentile and the 75th percentile of the EMG onsets. Onset is relative to the initiation of the movement during (a) leg lift with no extra external weight. Ten women performed the leg lift; two were excluded due to increase in background activity of the PFM; n for PFM = 8; n for HA = 8; n for TrA/OI = 7\*; n for RA = 8; n for RF = 8; (b) leg lift with the extra 2-kg weight. Eight women performed the leg lift with the extra 2-kg; two were excluded due to increase in background activity of the PFM; n for PFM = 6; n for HA = 6; n for TrA/OI = 6; n for RA = 5\*; n for RF = 6; (c) arm lift. Ten women performed the arm lift; one was excluded due to increase in background activity of the PFM; n for PFM = 7\*\*; n for HA = 4\†\†; n for TrA/OI = 3\†\*; n for RA = 6\†.
Footnote to Figure 1
* one woman lacked EMG onset of the muscle
** two women lacked EMG onset of the muscle
† three women lacked EMG onset of the muscle
†† five women lacked EMG onset of the muscle
††† six women lacked EMG onset of the muscle

EMG Electromyographic
PFM Pelvic floor muscles
HA Hip adductors
TrA/OI Transversus abdominis/Internal oblique muscle
RA Rectus abdominis muscle
ES Erector spinae muscle
RF Rectus femoris muscle

3.2 Arm lift

In median, the postural response for all muscles except the rectus abdominis muscle occurred before the initiation of the arm lift (Fig. 1). The background activity in the PFM was increased in one woman and this made it difficult to detect the EMG onset with the algorithm used and she was excluded from further analyses. Five of the nine women presented EMG onsets of the PFM before the lift had begun and two women presented EMG onset after the start of the arm lift. Two women were considered to have no onset of the PFM since they presented three or more onsets of the PFM 400 ms after the initiation of the arm lift.

Five of the nine women lacked EMG onset in the hip adductors, six of the nine women lacked an EMG onset of the transversus abdominis/internal oblique muscle and three of the nine women lacked an onset of the rectus abdominis muscle during the arm lift.

The activation level of the PFM ranged between 9% and 36% of the MVC during the arm lift with the median value 23% (Fig. 2).
Fig. 2. The median, the 25th percentile and the 75th percentile of the relative EMG activation amplitude (i.e. relative value of one muscle = peak value during a movement/peak value during the MVC) during: (a) leg lift with no extra weight. Ten women performed the leg lift; two were excluded due to increase in background activity of the PFM. (b) leg lift with the extra 2-kg weight. Eight women performed the leg lift with the extra 2-kg; two were excluded due to increase in background activity of the PFM. (c) arm lift. Ten women performed the arm lift; one was excluded due to increase in background activity of the PFM. MVC Maximal voluntary contraction; PFM Pelvic floor muscles; HA Hip adductors; TrA/OI Transversus abdominis/Internal oblique muscle; RA Rectus abdominis muscle; ES Erector spinae muscle; RF Rectus femoris muscle; DE Deltoid muscle
4. Discussion
The findings suggest that a feed-forward mechanism can be demonstrated in the PFM as a response to a postural challenge in women who had previously given birth and who did not suffer of lumbopelvic pain. The feed-forward response was found both as a response to the initiation of the leg lift with, and without the extra 2-kg weight, and during the arm lift. Although not all women presented EMG onsets of the PFM prior to the initiation of the lifts, the majority of the women presented EMG onsets as a response to the initiation of the different limb movements. To our knowledge no other studies have investigated the feed-forward mechanism of the PFM during limb movements performed at a comfortable speed.

A similar feed-forward response in the PFM during arm movements have previously been shown by Hodges et al. (2007) and by Smith et al. (2007a), however they did not find as early EMG onsets as we found. That may be due to differences in methodology used in the studies. Hodges et al. (2007) and Smith et al. (2007a) related the EMG onset of the PFM to the prime mover rather than the initiation of the movement. Unfortunately we had to exclude the deltoid muscle, i.e. the prime mover, from the analyses of the EMG onsets due to increased background activity and we can therefore not compare the time of our EMG onsets of the PFM to the result found by Hodges et al. (2007) and Smith et al. (2007a). However, when looking at the EMG onset of the PFM in relation to the prime mover during the leg lifts our results are more similar with the results of Hodges et al. (2007) and Smith et al. (2007a).

The median value of the EMG onset of the PFM was 45 ms and 64 ms and occurred before the rectus femoris during the leg lift with and without the extra 2-kg weight, respectively. It is possible that our results in the arm lift would have been more similar to the ones Hodges et al. (2007) and Smith et al. (2007a) found if we had been able to relate the EMG onset of the PFM to the EMG onset of the deltoid muscle in addition to the initiation of the movement.
Another possible explanation for the difference of the time for the EMG onset of PFM could be that we instructed the women to perform the movement at a comfortable speed. In the studies by Hodges et al. (2007) and by Smith et al. (2007a) the subjects were asked to perform the movement rapidly. However, since we want to apply the method on women with lumbopelvic pain we want to develop a method that can be used without triggering the pain more than necessary. It was also an attempt to make the standardized movements more functional. Hodges and Richardson (1997b) have found that pre-programmed trunk muscle activity is associated with both self-paced and rapid upper limb movements, although the speed of the movement did influence the time of the onset.

When detecting onset by computer, the onset is likely to be influenced by the rate of increase of activation level (Walter, 1984). An increase in muscle activity should occur irrespectively of speed even though the activity level might differ. To validate the response in terms of activation level we have used different loadings, i.e. leg lifts performed in supine with and without an extra weight and arm lift performed in standing position. The activation level has varied with the different tasks depending on the postural demand and this verifies that the method is useful to detect increases in the activation amplitude. The fact that Hodges et al. (2007) and Smith et al. (2007a) used visual analyses to detect EMG onsets and we used a computer-based method should not have made any difference since the two methods are comparable (Hodges and Bui, 1996). To summarize, even if there are some differences in comparison to other studies, our study confirms the findings of a feed-forward mechanism in the PFM.

It has been argued that the increase seen in the EMG recordings of the PFM could be a result from an increase of the intra-abdominal pressure and not an increase in the muscle activation.
This is based on the fact that the PFM is one of the adjunctive closure mechanisms that maintain continence during an elevation in the intra-abdominal pressure (Bernstein, 1997) and an elevated intra-abdominal pressure is related to an increase of the spinal stiffness (Cholewicki et al., 1999). However, studies have investigated the relation between an increase in the intra-abdominal pressure and the EMG activity of the PFM during different tasks and the results have demonstrated that the activity in the PFM is more closely related to the activity of the abdominal muscles than the intraabdominal pressure (Hodges et al., 2007; Neumann and Gill, 2002).

We used surface EMG to record the muscle activation. Surface EMG has several advantages over intramuscular EMG, but several methodological difficulties must be considered. The PeriformTM vaginal probe has a better between day reliability than the FemiscanTM vaginal probe (bipolar configuration), which is also widely used to record the activation of the PFM (Brown and McLean, 2008). Both surface electrodes have less variability between trials compared to fine-wire electrodes (Brown and McLean, 2008). Overhearing from adjacent muscles has been suggested to be a possible source of cross-talk when recording EMG activity of the PFM (Bo and Stein, 1994, Peschers et al., 2001; Sapsford and Hodges, 2001). However, no cross-talk has been observed from either the hip or the abdominal muscles when recording EMG activity of the PFM with the PeriformTM vaginal probe (Hodges et al., 2007; Smith et al., 2007b). We have also investigated the possibility of cross-talk between the abdominal muscles and the PFM as well as between the hip adductors and the PFM in a pilot study (unpublished). If the correlation between the EMG activation of the PFM and the deep abdominal muscles or between the PFM and the hip adductors could be visually detected, recording the EMG activity of the PFM could be a risk for cross-talk. No such correlations were detected in the pilot study suggesting that the risk of crosstalk was minimal. It is
possible that some previous studies that have reported possible cross-talk from hip or abdominal muscles may have erroneously interpreted synergistic muscle activation as cross-talk. Another problem related to surface EMG is artefacts that can arise from skin movements, the wire leads connecting the electrode to the amplifiers, and the electrostatic fields in our environment (Basmajian and DeLuca, 1985). To minimize the disturbance we have used ground electrodes, taped the electrodes to reduce electrode movements and placed amplifiers approximately 10 cm from each electrode site. In addition, various filtering procedures have also been used to minimize artefacts such as electrocardiogram (Turker, 1993).

The aim of the method we used is to be able to detect a possible dysfunction in the PFM to investigate if women with lumbopelvic pain after pregnancy have a different activation pattern compared to women with no lumbopelvic pain. A possible dysfunction in the PFM might decrease the force closure and lead to difficulties in maintaining the lumbopelvic stability (Pool-Goudzwaard et al., 2004). Smith et al. (2007a,b) and Thompson et al. (2006) have identified PFM dysfunction, such as stress urinary incontinence with surface EMG, which strengthen that a PFM dysfunction can be observed with surface EMG.

The difficulty to detect the EMG onset of the PFM in two women at the initiation of the arm lift can be due to either measurement problems or a possible lack of onset. Measurement problems could be a result of difficulties in standardizing the arm lift or it is possible that the lack of onset is due to greater postural demand from standing compared to supine position. It is also possible that not all women without lumbopelvic pain have a feed-forward manner in the PFM during limb movements performed at comfortable speed. No onsets could be detected visually in the PFM and this strengthens the hypothesis of a possible lack of onset in the PFM and not a result of measurement problems. Marshall and Murphy (2003) have
demonstrated that people without low back pain do not necessarily have a feed-forward manner with a pre-activation of the transversus abdominis/internal oblique muscle during rapid limb movements.

5. Conclusion

In conclusion, the findings suggest a feed-forward activation of the PFM during limb movements performed at a comfortable speed. The feed-forward activation was found in women who previously had given birth and who had not suffered from lumbopelvic pain over the previous 12 months. For the majority of the women the feed-forward manner could be detected both during the leg lifts performed while supine and during the arm lift performed while standing. However, it was more difficult to observe it during the task performed in standing position and due to the small number of women, more studies are required to confirm the results. Future studies should also focus on applying the method to women with lumbopelvic pain persisting after giving birth and compare them with women without any lumbopelvic pain. Identification of sub-groups and understanding of the underlying mechanism of lumbopelvic pain would facilitate the development of targeted interventions for this large group of patients.

Conflict of interest statement

There are no financial or personal relationships between any of the authors with any organisations or other people that could have inappropriately influenced the work.
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