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論文題目：	腰痛により日常生活に困難を感じている妊婦の個別性に合わせた介入方略の開発と検証 Development and Verification of an Intervention Strategies Individually Tailored to Pregnant Women whose Daily Life was Affected by Lower Back Pain		
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博士論文要旨

妊娠初期から妊婦の約6割が腰痛を自覚し、妊娠末期には8割に達するが、医療者から適切なアドバイスが得られず、十分なセルフケアができていない現状にある。妊婦の腰痛は、その発生機序に働きかける介入を中心として提供されるが、妊婦が腰痛に対処するためには、いくつかの方法を組み合わせる多様な要因に働きかける必要がある。さらに、妊婦がそれらを生活の中で調整して行えるよう支援する必要がある。なお、本研究における「妊婦の腰痛」は、妊娠に関連して生じる腰痛、骨盤痛、および腰骨盤痛とした。

【目的】

本研究は、腰痛により日常生活に困難を感じている妊婦が、自分に合った方法により腰痛に対処できるよう支援する看護の介入方略を開発し、検証することを目的としている。

【方法】

本研究のデザインは、無作為化比較試験である。介入として用いた方略は、Oremのセルフケア不足看護理論を理論枠組みとして開発し、セルフケア・エージェンシーとセルフケア・デマンドの不足部分に対して、妊婦が「気づく・わかる」「判断し意思決定する」「セルフケアを実行する」「セルフケアを評価し再調整する」の4つのステップを自らできるように支援するものである。これを、2週間毎に実施される妊婦健康診査時に3回提供することとした。研究対象は、妊娠28～31週の単胎妊婦で、腰や骨盤部に痛みがあることで日常生活に困難を

感じている妊婦とした。

対照群は研究協力施設医療者による通常ケアを受け、介入群は研究協力施設医療者による通常ケアに加えて研究者による介入を受けた。介入の主要評価項目は、疼痛強度 (Numerical Rating Scale (NRS))、痛みの性質 (Short-Form McGill Pain Questionnaire (SF-MPQ))、痛みの心理的要因 (痛みの破局的思考 (Pain catastrophizing scale: PCS))、疾患特異的日常生活動作 (Roland-Morris Disability Questionnaire (RDQ))、日本整形外科学会腰痛評価指標 (Japanese Orthopaedic Association Back Pain Evaluation Questionnaire: JOABPEQ))、腰痛への対処状況 (腰痛対処法の有無、持っている対処法の数、対処法の評価) である。これらは、研究協力の同意を得た時 (事前調査) と、4 週間後の 3 回目の妊婦健康診査終了後 (事後調査) に調査した。

基礎情報、主要評価項目、副次評価項目は両側検定にて危険率 5%未満を有意水準とした。妊婦の個別性に合わせた介入の分析は、フィールドノートと任意記載の日記から、査定と妊婦に提供した方略をカテゴリー化し、介入時の妊婦の反応と実施状況はそのパターンを抽出した。本研究は、兵庫県立大学看護学部・地域ケア開発研究所研究倫理委員会の承認 (2015 年申請番号: 博士 2) を得たうえで、研究協力施設における研究倫理審査を受け、承認を得て実施した。

【結果および考察】

妊婦 72 人から研究協力の同意が得られ、介入群 36 人と対照群 36 人に無作為割り付けを行った。調査終了妊婦は介入群 30 人 (83.3%)、対照群 29 人 (80.5%) であった。介入群と対照群では初経産の割合に有意差が生じ、介入群に初産婦、対照群に経産婦が多くなった。他の基礎情報に有意な違いはなく、初・経産婦別でも群間に違いはなかった。事前調査時の主要評価項目は、介入群と対照群に有意な違いはなかった。初経産婦別では、初産婦は介入群と対照群に違いはなかったが、経産婦において対照群が介入群より痛みの性質 (SF-MPQ) の下位項目の「感情的痛み」平均得点が有意に高かった。本研究で得られた結果および考察は以下のとおりである。

1. 介入群は対照群より事後調査時の「現在の痛み」と「1 週間平均の痛み」および「腰痛による今日の日常生活への支障 (RDQ)」の平均得点が有意に減少した。「1 週間平均の痛み」、「腰痛による今日の日常生活への支障 (RDQ)」、および「腰痛によるここ 1 週間の日常生活への支障 (JOABPEQ) -疼痛関連障害」の事前事後の得点変化を臨床上有益な最小変化 (MCID) で効果判定すると、介入群の臨床的に改善した妊婦は対照群より有意に多かった。「腰痛による今日の日常生活への支障 (RDQ)」の MCID 判定の結果、改善できた妊婦と MCID の変化は示さなかったが支障なしと判定できた妊婦を「RDQ 改善 or 支障なし妊婦」としたところ、「RDQ 改善 or 支障なし妊婦」は介入群 17 人 (56.7%)、対照群 4 人 (13.8%) であり、「RDQ 非改善妊婦」は介入群 13 人 (43.3%)、対照群 25 人 (86.2%) と有意に違っていた。各群の事前事後比較では、「1 週間で一番の痛み」の平均得点は介入群で有意に減少した

が対照群に変化はなく、「腰痛による今日の日常生活への支障（RDQ）」の平均得点は介入群が有意に減少し、対照群が有意に増加した。痛みの性質（SF-MPQ）の平均得点の変化量は介入群が減少し、対照群が増加し、両群の変化量には有意な違いがあった。介入群は対照群より事後調査時に対処法を有する人数が有意に多くなり、妊婦が実施している対処法の数と対処法を評価した得点が有意に高くなった。事前事後比較において、介入群は妊婦が実施している対処法の数と対処法を評価した得点が有意に増加したが、対照群は変化がなかった。

介入群の妊婦は、妊婦健康診査で介入を受けることにより、効果があると本人が評価する対処法を複数持つことができ、対照群よりも疼痛強度や日常生活への支障を有意に軽減することができた。一方、通常ケアのみの対照群は、対処法の数や対処法を評価した得点、および疼痛強度に変化が無く、日常生活への支障が悪化したことから、本研究で提供した個別性に合わせた介入方略は、腰痛により日常生活に困難を感じている妊婦の腰痛対処状況を変化させ、痛みや生活の状況を改善したといえる。

2. 妊婦の個別性に合わせた介入方略における査定は、腰痛対処実施状況の査定、腰痛対処に影響を与える要因の査定、方法提案に活かす要因の査定、対処法実施による効果の査定に分けられた。腰痛対処実施状況の査定では【有効な方法の実施】【有効でない方法の実施】【バリエーションの不足】、腰痛対処に影響を与える要因の査定では【知識の不足】【エネルギーの不足】【新規の痛みや辛さ】、方法提案に活かす要因の査定では【腰痛を起こしにくい体の状態】【腰痛を起こしやすい体の状態】【痛み以外に対処が必要な心身の状態】【対処する上での強み】、対処法実施による効果の査定では【痛みが改善し対処できている】【痛みの軽減はあるがさらに工夫が必要】【痛みの軽減なく工夫が必要】【パワー構成要素の高まり】を査定した。妊婦に提供した方略は【エネルギー不足に応じた介入内容の調整】【対処できている方法の支持と強化】【有効でない方法の確認と調整】【特性に応じた方法の提案】であった。初回の介入では、腰痛対処に影響を与える要因の査定のうち【知識の不足】と【エネルギーの不足】を査定した上で、腰痛対処実施状況、方法実施に活かす要因、対処法実施による効果の査定を行い、提供する方略を決定した。2・3回目の介入では、腰痛対処に影響を与える要因の査定に【新規の痛みや辛さ】の査定と、対処法実施による効果の査定に【パワー構成要素の高まり】の査定が加わった。

本研究により、妊婦の腰痛に対して看護職が行う必要のある査定項目が明らかになった。腰痛を抱え困難を感じている妊婦には、まず知識の確認と対処しうるエネルギーの存在を確認する必要がある。さらに、腰痛対処実施状況や方法提案に活かす要因の査定をすることで、どのような調整・工夫があれば本人が腰痛に対処可能になるかを査定し、査定を踏まえた方法の提案が必要である。また、本研究で明らかとなった査定項目や方略は、腰痛により

日常生活に困難を感じている妊婦を支援する際の視点となる。

3. 介入群の「RDQ 改善 or 支障なし妊婦」の査定項目の該当割合は、【有効な方法の実施】が初回 58.8%から 3 回目 88.2%、【有効でない方法の実施】が初回 47.1%から 3 回目 35.3%、【新規の痛みや辛さ】が 2 回目 23.5%から 3 回目 17.6%、【パワー構成要素の高まり】が 2 回目 64.7%から 3 回目 76.5%に変化し、【痛みの軽減なく工夫が必要】が初回 94.1%であったが 3 回目の該当者はいなかった。「RDQ 非改善妊婦」では、【有効な方法の実施】が初回 61.5%から 3 回目 92.3%、【有効でない方法の実施】が初回 53.8%から 3 回目 76.9%、【新規の痛みや辛さ】が 2 回目 38.5%から 3 回目 76.9%に変化し、【パワー構成要素の高まり】が 2 回目 3 回目ともに 46.2%で、【痛みの軽減なく工夫が必要】が初回 92.3%から 3 回目 15.4%であった。「RDQ 改善 or 支障なし妊婦」は、腰痛に対処し得る方法が実施でき、11 人の妊婦は調査を実施した 4 週間に新たな痛みや辛さが生じていず、4 人の妊婦は新規の痛みや辛さがあっても対処できていた。一方、「RDQ 非改善妊婦」は、腰痛に対処し得る有効な方法を実施することができていたが、10 人の妊婦は調査期間中に新たな痛みや辛さが生じ、その痛みや辛さに対処し得る有効な方法の実施までは至っていなかった。

腰痛により日常生活に困難を感じている妊婦は、腰痛に対処できる力を得る必要がある。看護職は妊婦の痛みの状況に合わせた対処法を妊婦に提供し、実施できるよう支援し、妊婦の腰痛に対処する方法のバリエーション不足を補う必要がある。加えて、妊娠経過や仕事、生活の変化に伴い新たな痛みや辛さが生じた時は、それに合わせた対処法を伝え、実施できるよう継続的に関わる必要がある。

【結論】

腰痛により日常生活に困難を感じている妊婦の個別性に合わせた介入方略は、妊婦の腰痛に対処し得る方法の数を増やし、有効な対処を可能とする能力を高め、疼痛強度や日常生活の支障を軽減できた。今後は、本研究で開発した介入方略を、妊婦健康診査等で看護職が活用できるようにしていく必要がある。そのためには、本研究で明らかにした査定や提供した方略をもとに、ケア提供できる看護職を育成することから始める必要がある。

Abstract

Background

About 60% of pregnant women experience lower back pain starting in the initial stages of pregnancy and up to 80% experience it in the final stages of pregnancy, but pregnant women do not receive appropriate advice from medical personnel and they are unable to practice adequate self-care. Pregnant women mainly receive interventions to address the mechanisms of lower back pain, but various factors need to be addressed with a combination of techniques to help pregnant women cope with lower back pain. Moreover, pregnant women need support so that they can incorporate those techniques into their lives. In the current study, “lower back pain in pregnant women” refers to lower back pain, pelvic pain, and lumbopelvic pain associated with pregnancy.

Purpose

One aim of the current study was to formulate care intervention strategies to support pregnant women whose daily life was affected by lower back pain so that they could use the techniques best suited to them to cope with lower back pain. Another aim of this study was to examine the effectiveness of those strategies.

Methods

The current study was designed as a randomized controlled trial. The intervention strategies were formulated with Orem’s self-care deficit nursing theory as a theoretical framework. In response to a deficit in self-care agency and unmet self-care demands, pregnant women would be given support in 4 steps to “recognize and identify” deficits and unmet needs, to “make decisions,” to “practice self-care,” and to “assess and adjust self-care.” This intervention was implemented 3 times during prenatal checkups conducted every 2 weeks. Subjects of this study were women with a singleton pregnancy at 28–31 weeks and whose daily life was affected by pain in the lower back or pelvic region.

The control group received the usual care by medical personnel at participating facilities. The intervention group received the usual care by medical personnel at participating facilities as well as the intervention by the current researchers. Primary endpoints for the intervention were pain intensity (assessed using a numerical rating scale (NRS)), pain characteristics (assessed using the Short-form of the McGill Pain Questionnaire (SF-MPQ)), psychological factors for pain (assessed using the Pain Catastrophizing Scale (PCS)), difficulties in daily life due to lower back pain (assessed using the Roland-Morris Disability Questionnaire (RDQ) and the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ)), and coping with lower back pain (whether techniques to cope with lower back pain are implemented or not, the number of coping techniques implemented, and assessment of coping techniques).

These endpoints were examined once subjects consented to participate in this study (preliminary study) and after the third prenatal checkup 4 weeks later (follow-up study). Tests of basic information, primary endpoints, and secondary endpoints were two-tailed with a significance level of $p < 0.05$. Interventions individually tailored to pregnant women were analyzed by categorizing the results of evaluations and strategies taught to pregnant women based on field notes and back pain journals. Patterns of responses to interventions by pregnant women and their implementation of those interventions were identified. This study was approved by the ethics committee of the College of Nursing Art and Science, University of Hyogo and the Research Institute of Nursing Care for People and the Community (2015 application no.: PhD2). This study was conducted with the review and approval of ethics committees at participating facilities.

Result and Discussions

Seventy-two pregnant women consented to participate in this study. These women were randomly assigned to an intervention group of 36 women or a control group of 36 women. This study was completed by 30 pregnant women in the intervention group (83.3%) and 29 in the control group (80.5%). There were significant differences in the ratio of primiparas and multiparas in the intervention group and the control group. There were more primiparas in the intervention group and multiparas in the control group. There were no significant differences in other basic information, and there were no differences between primiparas and multiparas in the two groups. During the preliminary study, there were no significant differences in primary endpoints for the intervention group and the control group. There were no differences in primiparas in the intervention group and control group, but multiparas in the control group had a significantly higher average score for “affective pain,” a subscale of pain characteristics (SF-MPQ), than the intervention group had. The results of this study and a discussion of those results are as follows.

1. During the follow-up study, average scores for “Your current level of pain,” “Your average level of pain during the week,” and “The impact of lower back pain on your daily life today (RDQ)” decreased significantly for the intervention group compared to the control group. Changes in scores for “Your average level of pain during the week,” “The impact of lower back pain on your daily life today (RDQ),” and “The impact of lower back pain on your daily life over the past week (JOABPEQ): Pain-related disability” before and after were determined using the minimal clinically important difference (MCID). Significantly more pregnant women in the intervention group benefited clinically than did women in the control group. Based on assessment of “The impact of lower back pain on your daily life today (RDQ)” using the MCID, pregnant women who benefited and pregnant women with no change in the MCID but no disability were deemed to be “Pregnant women with

a better RDQ score or no disability.” Seventeen pregnant women in the intervention group (56.7%) and 4 pregnant women in the control group (13.8%) had “a better RDQ score or no disability” while 13 women in the intervention group (43.3%) and 25 women in the control group (86.2%) had “an RDQ score that had not improved,” so the groups differed significantly. A before-and-after comparison of each group indicated that the average score for “the most intense pain during the week” decreased significantly for the intervention group but did not change for the control group. The average score for “The impact of lower back pain on your daily life today (RDQ)” decreased significantly for the intervention group but increased significantly for the control group. Intervention group decreased the amount of change of the scoring average of the pain characteristics (SF-MPQ), and control groups increased, and there was significant difference in the amount of change of both groups. During the follow-up study, more pregnant women in the intervention group implemented coping techniques than pregnant women in the control group. Moreover, pregnant women in the intervention group implemented more coping techniques and had higher scores for their coping techniques. According to a before-and-after comparison, pregnant women in the intervention group implemented more coping techniques and had significantly higher scores for their coping techniques, but there were no changes in the control group.

Pregnant women in the intervention group received interventions during prenatal checkups, and those women considered a number of coping techniques to be effective. Pain intensity and the impact of lower back pain on one’s daily life decreased significantly for pregnant women in the intervention group compared to pregnant women in the control group. In contrast, there were no changes in the number of coping techniques implemented, scores for coping techniques, or pain intensity in the control group, which received the usual care alone. Lower back pain also had significantly more of an impact on the daily life of pregnant women in the control group. Individually tailored intervention strategies formulated in the current study changed how pregnant women coped with lower back pain. Those strategies also alleviated their pain and improved their lives.

2. Evaluation of intervention strategies individually tailored to pregnant women was divided into an evaluation of coping with lower back pain, an evaluation of the factors affecting coping with lower back pain, an evaluation of the factors involved in devising coping techniques, and an evaluation of the effectiveness of implementing coping techniques. Evaluation of coping with lower back pain examined “Implementing effective techniques,” “Implementing ineffective techniques,” and “A lack of variation.” Evaluation of the factors affecting coping with lower back pain examined “A lack of knowledge,” “A lack of energy, and “New

pain or hardships.” Evaluation of the factors involved in devising coping techniques examined “Becoming less physically susceptible to lower back pain,” “Becoming more physically susceptible to lower back pain,” “Having to cope with a mental or physical problem other than pain, and “The advantages of coping.” Evaluation of the effectiveness of implementing coping techniques examined “Being able to cope since one’s pain has been alleviated,” “Having less pain but wanting to know additional tips,” “Wanting to know tips since one’s pain has not changed,” and “Enhancing the ‘power components’ of self-care agency.” Strategies taught to pregnant women involved “Adjusting the intervention in accordance with a lack of energy,” “Encouraging and improving successful coping techniques,” “Verifying that techniques were ineffective and adjusting those techniques,” and “Devising techniques in accordance with the individual’s attributes.” At the first intervention, “A lack of knowledge” and “A lack of energy” were evaluate factors affecting coping with lower back pain. Coping with lower back pain, the factors involved in implementing coping techniques, and the effectiveness of implementing coping techniques were evaluated, and strategies were formulated. At the second and third interventions, “New pain or hardships” was evaluated as a factor affecting coping with lower back pain, and “Enhancing the ‘power components’ of self-care agency” was added to evaluation of the effectiveness of implementing coping technique.

The current study revealed items that nurses need to evaluate with regard to lower back pain in pregnant women. Nurses need to verify that pregnant women who are suffering from lower back pain know how to cope with that pain and that those women have the energy to do so. Moreover, coping with lower back pain and factors involved in devising coping techniques need to be evaluated, and the adjustments and approaches that allow those women to cope with lower back pain need to be evaluate. Techniques then need to be devised based on those evaluations. In addition, the evaluations and strategies identified in the current study provide a perspective on supporting pregnant women whose daily life is affected by lower back pain.

3. Of the “Pregnant women with a better RDQ score or no disability” in the intervention group, 58.8% were assessed as “Implementing effective techniques” at the first intervention while 88.2% were so assessed at the third intervention, 52.9% were assessed as “Implementing ineffective techniques” at the first intervention while 35.3% were so assessed at the third intervention, 23.5% were assessed as having “New pain or hardships” at the second intervention while 17.6% were so assessed at the third intervention, and 64.7% were assessed as “Enhancing the ‘power components’ of self-care agency” at the second intervention while 76.5% were so assessed at the third intervention. Ninety-four-point-one percent of pregnant

women were “Wanting to know tips since one’s pain has not changed” at the first intervention but there were no such women at the third intervention. Of the “Pregnant women with an RDQ score that had not improved,” 61.5% were assessed as “Implementing effective techniques” at the first intervention while 92.3% were so assessed at the third intervention, 53.8% were assessed as “Implementing ineffective techniques” at the first intervention while 69.2% were so assessed at the third intervention, 30.8% were assessed as having “New pain or hardships” at the second intervention while 61.5% were so assessed at the third intervention. Forty-six-point-two percent of pregnant women responded that they were “Enhancing the ‘power components’ of self-care agency” at both the second and third intervention. Ninety-two-point-three percent of pregnant women responded that they were “Wanting to know tips since one’s pain has not changed” at the first intervention while 15.4% were so assessed at the third intervention. “Pregnant women with a better RDQ score or no disability” implemented techniques that allowed them to cope with lower back pain, and 12 pregnant women had no new pain or hardships during the 4 weeks when the study was conducted. In contrast, “Pregnant women with an RDQ score that had not improved” were able to implement effective techniques to cope with lower back pain, but 8 pregnant women had new pain or hardships during the period of this study, and they were unable to implement techniques to effectively cope with that pain or those hardships.

Pregnant women whose daily life has been affected by lower back pain need to acquire the ability to cope with that pain. Nurses need to teach pregnant women coping techniques tailored to the state of their pain, nurses need to help those women implement those techniques, and nurses need to compensate for the lack of variation in techniques for pregnant women to cope with lower back pain. When new pain and hardships arise over the course of pregnancy or in conjunction with changes at work and in life, nurses need to teach corresponding coping techniques to pregnant women and continuously interact with those women to help those women implement those techniques.

conclusion

Intervention strategies individually tailored to pregnant women whose daily life was affected by lower back pain increased the number of techniques those women used to cope with that pain, those strategies increased the ability of those women to cope effectively, and they reduced pain intensity and the impact that pain had on their daily life. In the future, nurses need to be trained to use the intervention strategies formulated in the current study in prenatal checkups. To that end, nurses need to be trained to provide care based on the evaluations and strategies identified in the current study.

論文審査の結果の要旨

本研究は、妊娠初期から妊婦の約6割が腰痛を自覚し、妊娠末期には8割に達するとされる妊婦の腰痛に着目し、日常生活において腰痛による支障を感じている妊婦に、個々の腰痛の状況に合わせた対処ができるよう妊婦を支援する介入方略を開発し、その有効性を検証することを目的とした。研究はOremのセルフケア不足看護理論をもとに、妊婦自ら「気づく・わかる」「判断し意思決定する」「セルフケアを実行する」「セルフケアを評価し再調整する」ことができるよう支援するという介入方略を作成し、無作為化比較試験により検証を行った。介入群の妊婦は、対照群よりも腰痛への対処法の数が有意に増え、疼痛強度や日常生活への支障の程度を有意に減らし、臨床上有益な最小変化（MCI D）を示した妊婦も介入群は対照群に比して有意に多かった。一方、対照群の妊婦は、疼痛強度に変化はなかったものの、日常生活への支障の程度が悪化したことから、作成した介入方略の効果を示すことができた。4週間の介入において介入効果が得られたことに加え、新たに生じた痛みに対処することが4週間の介入だけでは難しく、腰痛を改善することができなかつた妊婦がいたこと、対照群の妊婦は腰痛による日常生活への支障が増したことから、妊娠経過に伴い腰痛が出現したり悪化したりする妊婦には、妊婦健康診査の場を活用して継続的に関わり、妊婦の状況に合わせた対処法を伝えることが必要であることを明らかにした。

審査会は、Oremのセルにケア不足理論をもとに、無作為化比較試験を実施し、妊婦個々の腰痛の状態に合わせた看護支援を提供し、妊婦自身が腰痛に対処可能な状況を作り出したこと、介入により疼痛の強度や生活の支障の程度を軽減させることができたことを高く評価した。今後、臨床での活用も期待でき、看護学の発展に資する学術的価値のある論文であるとした。