The Impact of Pharmacist Interventions on Osteoporosis Management: A Systematic Review

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Osteoporosis

• “Silent thief”

• Microarchitectural deterioration of bone tissue

• Increases fracture risk

• Prevalence of disease increases with age
  - 25% of Canadian women
  - 13% of Canadian men
Gaps in Osteoporosis Management

1) Identification of at-risk patients
   • <½ of patients post-fracture are diagnosed
     • Pharmacists may help identify high-risk patients (such as those on chronic glucocorticoid therapy) who can then be targeted for bone mineral density (BMD) testing.

2) Treatment and adherence to treatment for osteoporotic patients
   • <40% persist with treatment at 1 year post-treatment
     • Pharmacists can provide counseling and educate patients on medication use, fall prevention, and the importance of calcium, vitamin D, exercise and adherence to therapy.
Methods

• Systematic literature review
• Electronic search
  – Key terms: related to pharmacy, osteoporosis
  – Databases: EMBASE, HealthStar, *International Pharmaceutical Abstracts*, MEDLINE, PubMed
  – Grey Literature: institutional and organizational websites
• Manual search
  – Reference lists of identified articles
Methods

• Inclusion Criteria
  – Osteoporosis management involving a pharmacist
  – Focus on evidence from randomized controlled trials (RCTs)
    – Highest quality of evidence

• Exclusion Criteria
  – Languages other than English
  – Abstracts, commentaries, news articles and review papers
Methods

• Examined threats to internal validity based on risk for bias
• Selection bias
  – Allocation bias
    • Randomization fails à comparison groups differ on important prognostic variables
  – Attrition bias
    • Patients who continue to be followed are systematically different from those who are lost to follow-up in ways that impact outcomes
• Information bias
  – Detection bias
    • Differential outcome assessment between comparison groups
  – Performance bias
    • Unequal provision of care between comparison groups other than differences related to the main intervention
Methods

• Level of risk of bias classified as:
  – Low
    • little evidence bias would impact study results
  – High
    • bias may have impacted study results
  – Medium
    • (no fine assessment)
Literature Search Strategy

Articles identified via electronic search (n=1072)*

- Duplicates removed (n=461)
  - Distinct articles identified (n=611)
    - Articles excluded (n=493)
      - title (n=403)
      - abstract (n=90)
  - Eligible studies from electronic search (n=118)
    - Identified from reference lists (n=1)
  - Eligible studies identified (n=119)
    - Articles excluded after content analysis (n=94)
      - abstracts/conference proceedings (n=15)
      - notes/summaries (n=12)
      - no primary data collection (n=14)
      - did not meet inclusion/exclusion criteria (n=37)
      - not located (n=9)
      - not in English (n=3)
      - other (n=4)
  - Articles identified (n=25)
    - RCTs (n=3)
| Study               | Design      | Country     | Setting                                                                 | Inclusion Criteria                                                                 | Groups | No. of Participants | Description                                                                                           |
|---------------------|-------------|-------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------|--------------------|-------------------------------------------------------------------------------------------------------|
| Crockett et al, 2008 | Cluster RCT  | Australia   | 6 suburb community pharmacies, 6 rural area community pharmacies         | • Age: Women >40 or men >50  
• No BMD test in previous 2 years  
• No previous OP treatment | Non-BMD | 84*                | Risk assessment done by comparing results from patient risk-factor questionnaire to protocol risk factors. Patients referred to general practitioners according to results from risk-assessment questionnaire. |
| McDonough et al, 2005 | Cluster RCT  | United States | 15 community pharmacies; treatment, n=8 control, n=7                      | • Age: ≥ 18  
• On at least 7.5mg of prednisone or equivalent for at least 6 months             | Treatment | 61*                | Patients received education and information pamphlet on risks of glucocorticoid-induced OP. Pharmacists monitored patients' drug therapy using the Outcomes Encounter Program. Identified problems were discussed with patient and/or prescribing physician. Physicians contacted with letter explaining program and providing them with communication form to pharmacies. Patients completed web-based questionnaire available in pharmacies at baseline and 9-months. |
## Results

| Study          | Design | Country | Setting          | Study Population and Description                                                                                           |
|----------------|--------|---------|------------------|---------------------------------------------------------------------------------------------------------------------------|
| Yuksel et al, 2009 | RCT    | Canada  | 15 community pharmacies | **Inclusion Criteria**<br>• ≥ 65 years of age or 50-64 with at least one major risk factor<sup>a</sup><br>• No BMD test in previous 2 years<br>• No current OP treatment |
|                |        |         |                  | **Groups**<br>**No. of Participants** 133<br>Usual care provided along with information material from OC. Patients asked to return to pharmacy at 16-weeks. |
|                |        |         |                  | **Intervention**<br>Appointments (30min) scheduled on clinic days. Patients provided with an educational program, educational materials from OC and pamphlet (designed by study investigators). Heel QUS was measured and results discussed with each patient. Patients encouraged to follow-up with their physicians and physicians were provided with study details, QUS results and information that their patient was eligible for BMD testing. Telephone follow-ups done at 2 and 8 weeks and patients asked to return to pharmacy at 16-weeks. |
# Results

| Study                     | Follow-up details                                      | Outcomes measured                              | Group 1 | Group 2 |
|--------------------------|--------------------------------------------------------|-------------------------------------------------|---------|---------|
|                          |                                                        |                                                 | n       | %       | n       | %       |
| Crockett et al. [34]     | 3-month telephone follow-up (patient self-report)      | Physician follow-up                             | 2/7     | 28.6    | 3/22    | 13.6    |
|                          |                                                        | Increase in calcium intake                       | 37/45   | 82.2    | 29/32   | 76.3    |
|                          |                                                        | Increase in vitamin D intake                     | 18/21   | 85.7    | 4/7     | 57.1    |
|                          |                                                        | Control, n=19                                    |         |         |         |         |
| McDonough et al. [35]    | 9-monthweb survey in pharmacy (patient self-report)    | DXA test                                        | –       | 39.2    | –       | 19.6*   |
|                          |                                                        | Bisphosphonate therapy                           | –       | 10.5    | –       | 9.1     |
|                          |                                                        | Calcium supplementation                          | –       | −6.9    | –       | 17.1*   |
|                          |                                                        | Control, n=19                                    |         |         |         |         |
| Yuksel et al. [36]       | 16 weeks, patient self-report in pharmacy (confirmed by DXA report and pharmacy dispensing records) | Primary outcome                                 | 14      | 10.5    | 28      | 21.7*   |
|                          |                                                        | DXA test or OP treatment                         | 13      | 9.8     | 28      | 21.7*   |
|                          |                                                        | New osteoporosis treatment                       | 3       | 2.3     | 6       | 4.7     |
|                          |                                                        | Additional patients meeting:                    |         |         |         |         |
|                          |                                                        | Calcium requirements                             | 25      | 18.8    | 39      | 30.2*   |
|                          |                                                        | Vitamin D requirements                           | 22      | 16.5    | 24      | 18.6    |

_BMD_ bone mineral density group (peripheral DXA), _DXA_ dual-energy X-ray absorptiometry, _OP_ osteoporosis

*p<0.05

*Percent change reported (from baseline to 9 months), calculated based on numbers presented in the paper. At baseline: 24% control vs. 52% intervention had a DXA test, and 0% control vs. 17% intervention used bisphosphonates.*
## Results

| Study                | Selection Bias | Information Bias |
|---------------------|---------------|------------------|
|                     | Allocation<sup>a</sup> | Performance<sup>c</sup> | Detection<sup>d</sup> |
|                     | Attrition<sup>b</sup> |                   |                         |
| Crockett et al. [34] | High          | High             | High                    |
|                     | • Better recruitment success in BMD group in rural regions (*n*=60 vs. *n*=43) | • Definition of risk differed between groups | • Self-report assessment based on patient recall of pharmacist recommendations and whether or not they complied with the pharmacist’s recommendations |
|                     | • Non-BMD group had larger proportion with history of low-trauma fracture (21% vs. 11%) | • Group 1: questionnaire only |                         |
| McDonough et al. [35] | High          | Low              | Low                     |
|                     | • Significantly more participants in intervention vs. control (*n*=70 vs. *n*=26) | • Little evidence that the “usual care” group differed outside the intervention | • Although outcomes are based on self-report, evidence suggests that self-report of DXA testing and bisphosphonate use is very good [49, 50] |
|                     | • Intervention group at higher risk, e.g.: a. Female (74% vs. 58%), b. Fracture history (30% vs. 12%) | • Follow-up: 87% intervention 73% control |                         |
| Yuksel et al. [36]  | Low           | Low              | Low                     |
|                     | • Intervention group had significantly more participants with family history of OP (47% vs. 34%) | • All participating pharmacists received training | • Self-report confirmed by DXA report from physician (test performed) and pharmacy records (prescription dispensed) |
|                     | • However, analyses adjusted for age, sex, and family history of OP | • However, all were accounted for in the analyses (intention to treat analysis) |                         |
|                     | Low           | Low              |                         |
|                     | • Attrition: 26 (20%) in intervention and 23 (17%) in control | • Control (“usual care”) group also given educational material, and thus, the effect may be larger than what was observed in the trial when compared to true “usual care” |                         |
Discussion

• Use of heel DXA measurement is a feasible BMD screening method that can be utilized by pharmacists
  – important for patient satisfaction and recruitment

• Community pharmacist interventions may help improve the identification of individuals at-risk of osteoporosis through DXA testing
Discussion

• **Strengths**
  – thorough systematic search of the literature
  – two independent reviewers
  – focus on RCT designs (our results are limited to the quality of generalizability of the RCT studies identified)

• **Limitations**
  – qualitative assessment of risk of bias
  – work is needed to provide better quality assessment tools for pharmacist interventions
Future Studies

• Further study is required to determine feasibility of interventions in community pharmacies, including generalizability and feasibility to other settings.

• Examine impact of intervention on osteoporosis treatment adherence.

• Examine pharmacists’ experience and satisfaction with osteoporosis management interventions.
ADDITIONAL SLIDES
Quality Assessment in Pharmacy Practice

Interventions

- Evaluation of methodological quality and study validity

- Lack of blinding:
  - increases bias assessment in methodological quality tools
  - underestimates quality of studies
  - potential solution: focus on allocation concealment rather than blinding (Charrios et al. 2009)
Scales to Assess Quality of Health Care RCTs

- **Downs and Black Scale**
  - 4 categories of assessment
    - Score for each item
      - 0 (no or unable to determine)
      - 1 (yes)
    - Quality score ratio

- **The Cochrane Collaboration’s Risk of Bias Tool**
  - Assesses 6 categories on level of risk of bias
    - Low risk of bias, Unclear risk of bias, High risk of bias
  - No score
  - Subjective to reviewer