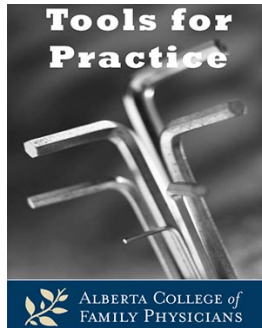


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## **Docusate: A Placebo Pill for Soft Poops**

**Clinical Question: Is docusate effective in the prevention and treatment of constipation?**

**Bottom line: Docusate appears similar to placebo in increasing stool frequency and is inferior to other products for treating functional, medication-induced, or post-operative constipation.**

### **Evidence:**

- Randomized Controlled Trials (RCTs) of both brands, docusate sodium (Colace™) and docusate calcium (Surfak™).
  - In functional or medication-induced constipation versus placebo:
    - 74 Palliative care patients (91% on opioids) on daily senna, received docusate or placebo.<sup>1</sup> Over 10 days:
      - No difference in daily bowel motions (BMs) or sense of complete evacuation.
    - 74 hospitalized patients (immobilized or semi-ambulatory) in cross-over RCT received docusate or placebo.<sup>2</sup> Over 30 days:
      - Docusate increased weekly BM by ~1/week.
      - No change in patient satisfaction.
      - Limitations: 26% lost to follow-up, statistics not performed, and study 60 years old.
    - Docusate sodium versus docusate calcium compared to placebo: Three week RCT in 46 elderly (mean age 82 years) institutionalized patients.<sup>3</sup>
      - Neither significantly changed number of weekly BMs (our calculation as misleading statistics reported).
    - Other placebo-controlled RCTs limited by:
      - Enrolled inappropriate patients (example comatose).<sup>4</sup>
      - Randomization not described<sup>5,6</sup> or incorrect (flipping coin).<sup>4</sup>
      - Patients and/or outcome assessors not likely blinded.<sup>4,5</sup>
      - Selective reporting on sub-group of patients.<sup>5,6</sup>
  - In functional or medication-induced constipation versus active comparator:
    - Docusate sodium versus psyllium: RCT of 170 patients (mean age 37 years, 92% females) over two weeks:<sup>7</sup>
      - Weekly BMs: Increased with psyllium (0.5/week), docusate no change.

- Post-operative patients:
  - Senna and docusate versus:
    - Placebo: First BM ~1 day sooner<sup>8</sup> with senna and docusate but benefit possibly due to senna.
    - Polyethylene glycol (PEG): First BM 1-2 days sooner with PEG.<sup>9</sup>
- Pregnant/post-partum patients:
  - No RCTs on docusate alone.<sup>10,11</sup>

#### Context:

- Constipation affects 12-19% of North American adults, most commonly children, elderly, and females.<sup>12</sup>
- Despite widespread prevalence, most constipation studies limited by small numbers and short study periods.
- Docusate use may be low (~6%) in primary care patients<sup>13</sup> but stool softener use more common (26%) in nursing home patients.<sup>14</sup>
- For comparison, osmotic agents increase BMs in adults and children by ~2-3 per week.<sup>15</sup>

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#### Disclosure:

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