Safety of blood donation from individuals with treated hypertension or non-insulin dependent type 2 diabetes: a systematic review

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CRD summary
This review found that overall evidence was limited, but that there was no evidence to indicate that high blood pressure, treated hypertension or diabetes were associated with any adverse effects on blood donors. The authors’ conclusions seem cautious, but potential for bias and the uncertain quality of the included studies should be taken into account when interpreting the conclusions.

Authors' objectives
To look for evidence on the safety of blood donation by people diagnosed with hypertension or diabetes.

Searching
The Cochrane Library (2008, Issue 1), MEDLINE, EMBASE, CINAHL, Biomolecular Interaction Network Database, Web of Science and NHS Blood and Transplant Systematic Review Initiative Handsearching Database were searched to February 2008. Search terms were reported. Conference abstracts of six relevant associations were checked. Papers were eligible if the abstract or full text was available in English.

Study selection
One reviewer screened search results and excluded clearly irrelevant references. Two reviewers assessed the full text of remaining papers.

Studies that reported on the safety of homologous or autologous blood donation with specific reference to blood pressure levels or where the donor was diagnosed with hypertension or diabetes (including any effects of medication) were eligible for inclusion. Studies that reported the effects of venesection of a standard donation unit (450 to 500mL) of blood from people with hypertension or diabetes were eligible.

Outcomes of interest were any reported adverse event, in particular vasovagal reactions, cardiovascular or cerebrovascular events and symptomatic haemodynamic changes during or following venesection of a standard unit.

Included studies were conducted between 1986 and 2006 in USA, Europe and Japan. Participants were general populations of donors and those with hypertension and diabetes, some of whom were on medication. Some were treated with venesection for therapeutic indications or for preoperative autologous donation.

Assessment of study quality
Study quality was assessed focusing on study design and interpretation of findings, impact of confounding factors and applicability of findings to current UK blood transfusion practice.

The authors did not state how many reviewers assessed study quality.

Data extraction
One reviewer extracted data. Differences in adverse effects between people with hypertension or diabetes and those without were extracted.

Methods of synthesis
Results were combined in a narrative synthesis. Differences between studies were listed in tables and discussed in the narrative.

Results of the review
Sixteen studies were included: one RCT (28 participants); four other experimental studies (75 participants); four case-controlled studies (2,233 participants); and seven prospective or retrospective observational studies (number of participants unclear).

None of the studies were designed to directly address the research question. Seven studies used blood collection methods applicable to current UK blood donations; no standard criteria were used for diagnosis or grading of adverse reactions. Of the observational and case controlled studies, only one satisfactorily addressed the effects of confounding factors. Although the experimental studies were generally of good quality, all were small and none directly addressed the review question.

None of the studies found any evidence of an increased risk to donors treated for hypertension or with baseline systolic blood pressure up to 200mm/Hg.

Very little data was available related to people with diabetes and none related specifically to those with non-insulin dependent type 2 diabetes. Two observational studies (which included 44 people with insulin dependent diabetes) found no evidence to indicate that diabetes was a predictor of adverse events. Two studies (one RCT and one experimental) that included 50 people with diabetes reported that venesection was well tolerated.

**Authors’ conclusions**
The overall level of evidence was limited. No evidence was found to indicate that blood donation by people with raised baseline blood pressure, treated hypertension or diabetes was associated with an increase in adverse effects in the donors.

**CRD commentary**
The review question was clearly stated, although study design was not specified. The search covered a number of relevant sources that included major databases and grey literature sources; this was likely to have reduced any effect of publication bias. As papers were excluded if they were published in languages other than English or did not have an English abstract, it was possible that language bias may have affected the review. The methods of study selection and data extraction did not aim at reducing reviewer error or bias. The quality of included studies was unclear and the authors did not state the methods used (such as how many reviewers performed the assessment). A narrative synthesis appeared appropriate given the diverse nature of included studies. Data came mainly from observational studies or small experimental studies; the authors commented on the limitations of data from these types of studies.

The authors’ conclusions seem cautious, but potential for bias in the review and the uncertain quality of the included studies should be taken into account when interpreting these conclusions.

**Implications of the review for practice and research**
**Practice:** The authors stated that the review supported the recommendations for changes to UK whole blood and component donor acceptance criteria to allow acceptance of donors with hypertension or diabetes.

**Research:** The authors stated a need for well-designed studies of adverse events in volunteer blood donors.

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