The sensitivity of PRO's in evaluating adverse events in people receiving "statin" therapy

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Aim:

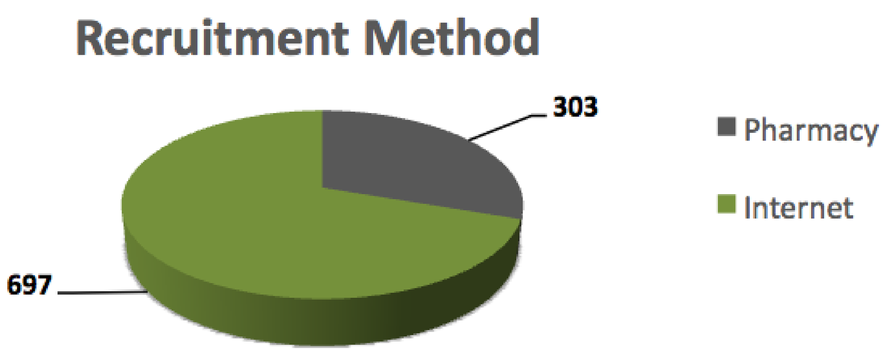
To investigate whether patient reported outcomes could report differences in adverse event rates of separate cholesterol lowering agents "statins". Whether patients could recall enough information to assess the differences.

Method:

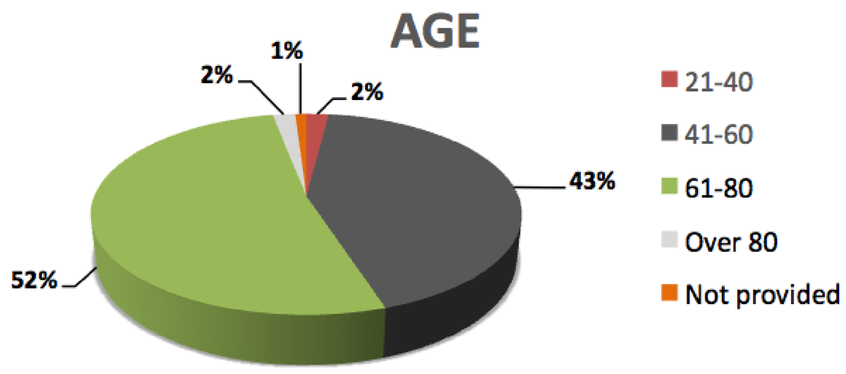
In this evaluation, ***PROBE*** (patient reported outcomes based evaluation) methodology consisting of a web-based system supplemented by telephone reporting was used to collect naturalistic data from people who were taking or about to start "statin" therapy. People were recruited through internet pay per click advertising, social networking sites and search engine optimisation. To compare recruitment rates and response quality we also recruited people through pharmacies with information leaflets. The comparison between the groups will be presented separately. Data collection was a one off questionnaire. Data included baseline demographics, therapy name, dose, cholesterol level before and after treatment, any side effects and action taken in response to side effect.

Results:

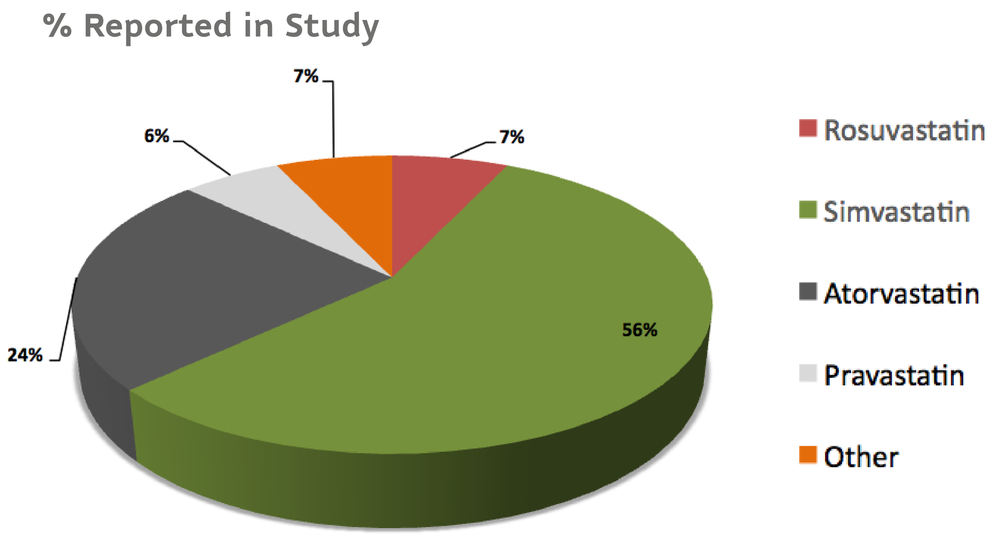
A total of 679 recipients participated in the evaluation.

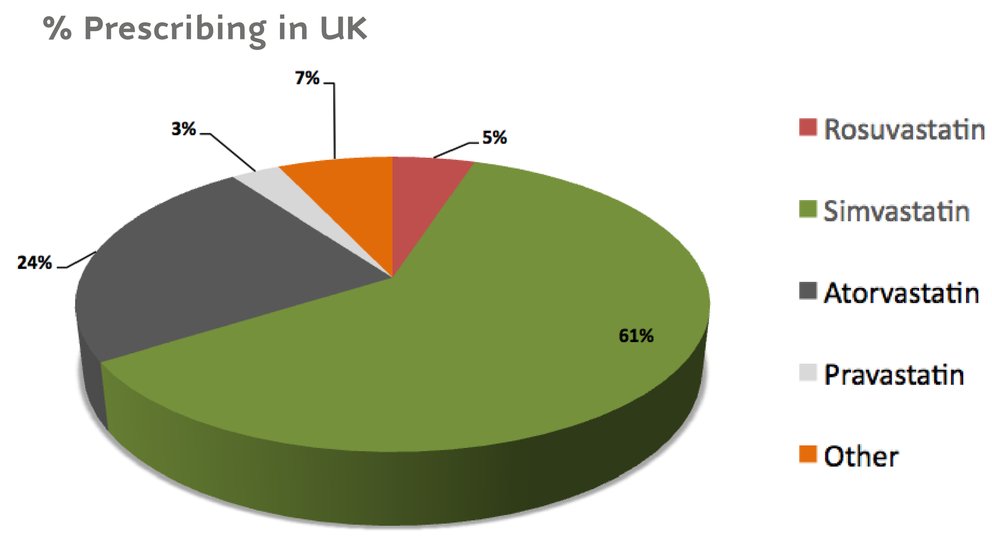


49% of participants were male with 43% aged between 41-60 and 52% between 61 -80.



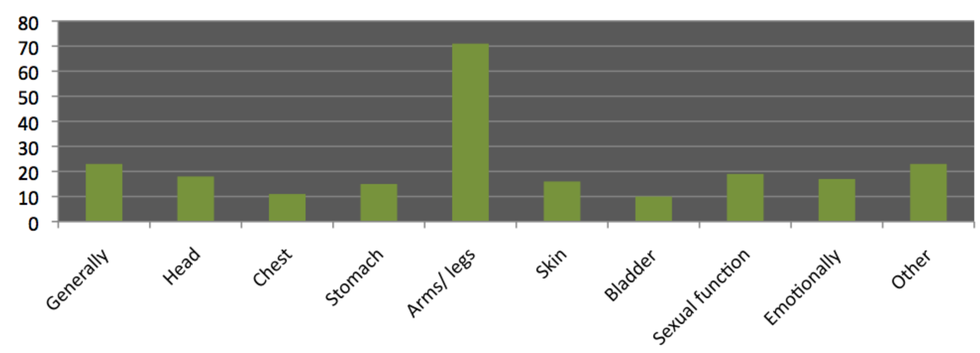
The reported use of cholesterol lowering agents mirrored dispensed prescription rates.



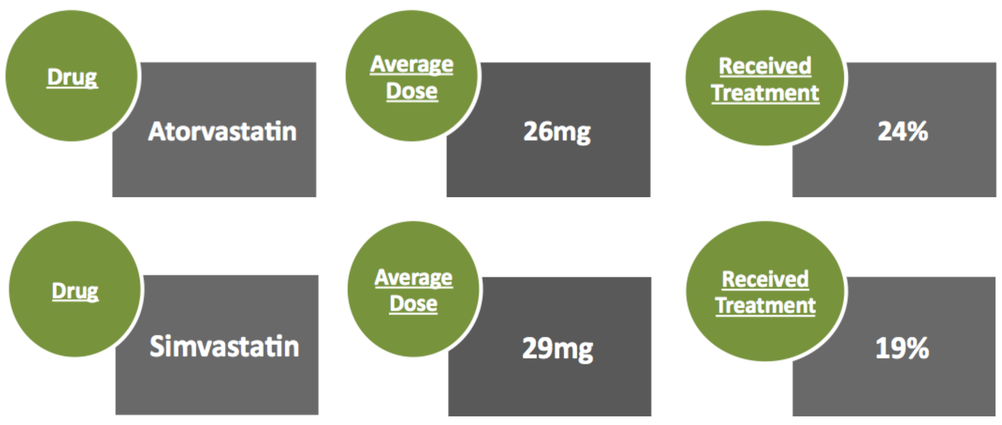


Side effects:

- **Overall, 336 (52%) of respondents felt they had experienced a side effect since commencing "statin" therapy with an average of 5 side effects per person.**
- **121 (18%) people reported that they required treatment with respect to the side effect, the commonest report being muscle pain in the arms or legs (28% of patients accounting for 39% of all side effects).**

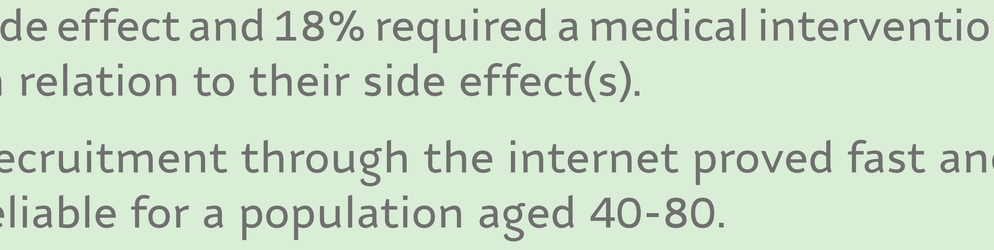


- **Interestingly, 24% of people on atorvastatin (mean dose 26mg) required treatment in relation to their side effect(s) as compared to 19% on simvastatin (mean dose 29mg).**



Cholesterol levels:

64% of people could recall their cholesterol before starting therapy and 94% supplied a meaningful figure.



Conclusions:

- This evaluation shows that the ***PROBE*** methodology captured patient reported outcome information on adverse events and patient actions in a population taking cholesterol lowering therapy.
- The population recruited was a representative sample of the population taking "statins" in the UK.
- Half the population receiving "statins" reported a side effect and 18% required a medical intervention in relation to their side effect(s).
- Recruitment through the internet proved fast and reliable for a population aged 40-80.