Chapter 3
PROSTAQUIL™ SAFETY STUDY: NON-INTERFERENCE WITH ANTICOAGULANTS & ANTIPLATELET AGENTS

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Antiplatelet agents and anticoagulants are increasingly used in the prevention of cardiovascular and thrombotic events.
This pilot study evaluates the effect of a new anti-inflammatory agent (based on Pygeum) on the antiplatelet action and anticoagulant activity in subjects using Prostaquil™ for benign prostatic hypertrophy (BPH) for at least two weeks.

The *in-vivo* bleeding time is performed with 2 small (2 mm) horizontal skin cuts; excess blood is removed using a filter paper and the time is recorded until bleeding stops.
The *bleeding time (BT)* (Duke) is a global test of platelet function and still regarded as the most clinically useful test of platelet function until the early 1990s. The bleeding time is the time taken for bleeding to stop after an incision is made into the skin, usually into the anterior surface of forearm. The test has been refined and standardized with the use of a sphygmomanometer cuff, room temperature control and a spring-loaded template device to make standard cuts within. Normal BT are usually between 2 and 10 min; severe platelet defects can result in a BT >30 min.
Despite its simplicity, the test needs attention to be reproducible.
In particular, the BT does not seem to correlate with the bleeding tendency within individual patients; an accurate bleeding history could be used as screening test. The advantage of the BT is that it does study natural hemostasis and the role played by the vessel wall in this process. The test does not require expensive equipment or a laboratory and is not prone to variables associated with blood sampling and anticoagulation.
In this registry, BT in 10 subjects (age 63.2;3.3 males; no other treatments or clinical conditions) before Prostaquil™

supplementation at the standard dosage - was on average 4.25;1 (range 3-6.5) min.
After 2 weeks of Prostaquil™ supplementation the value was 4.22;1.2 (range 3.1-6) min. Aspirin (Cardioaspirin 100 mg/day) had been used in the two weeks of Prostaquil™ management (these patients had been in chronic antiplatelet management for at least 6 months and had no tolerability problems).
Comparable results were obtained with Plavix (7 patients) and ticlopidine (8 patients) who used the antiplatelet agents at their standard dosages with a variation in BT of less that 2% (lower than the variability value for the test).

Anticoagulation was evaluated in 10 patients using Coumadin. Before the two weeks with the supplement their international normalized ratio (INR) was on average 2.94;0.2; after 2 weeks with the supplement the INR was basically unchanged (2.95;0.13).
New anticoagulants are now in the market expanding their applications. Therefore, studies are also looking at these new products.

In conclusion, Prostaquil™ – in this pilot evaluation – does not change the antiplatelet action of the most common antiplatelet agents and does not seem to alter, in stable anticoagulated patients, the needed dosage of anticoagulant treatment after two weeks of supplementation.

References

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