

Heparin Diversification! Sheep Heparin is an Alternate for Porcine Heparin

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Unfractionated heparin is the most widely used anticoagulant drug for the surgical and interventional indications. Unfractionated heparin and low molecular weight heparin are widely used for the management of thrombotic and cardiovascular disorders. Unfractionated heparin has remained the anticoagulant of choice for surgical and interventional use. Most of the heparins are derived from pig mucosa (porcine mucosa) however heparin from other sources has also been manufactured from other mammalian sources such as bovine (cow) and ovine (sheep). Although most of the heparins used globally are obtained of porcine origin, bovine and ovine heparins have also been used in unregulated markets. The North American and European community primarily use heparins derived from porcine sources which are primarily of Chinese origin. Worldwide there are 1.4 billion cattle, 1.9 billion sheep and goats and 980 million pigs. Both cow and sheep provide alternate sources of heparin which are not widely used due to regulatory reasons. The FDA is currently considering the introduction of bovine unfractionated heparin. Sheep heparin provides an additional source of this important drug and is currently under development. Unfractionated sheep heparin is found to be comparable to the porcine heparin in terms of its anticoagulant activity. The specific activity of sheep heparin is around 200 USP u/mg which is comparable to porcine heparin. In other studies sheep heparin is found to be comparable to porcine heparin in terms of molecular weight, biological activities and neutralization profiles. De-polymerization of sheep heparin has provided comparable low molecular weight heparins which are derived from porcine mucosal heparin. Although the structural profile of sheep heparin might be slightly different however the biological activities of sheep heparin are comparable to porcine heparin. In comparison to bovine heparin, sheep heparin is closer to porcine heparin. Extensive studies on the structural characterization and functional properties have been found to be similar in both sheep and porcine heparin. In particular enoxaparin derived from sheep heparin is comparable to enoxaparin derived from porcine heparin. The potency of sheep heparin is around 100 u/mg in terms of anti-Xa and 35 u/mg in the anti-Xa assays which is similar to porcine counterparts. These studies clearly demonstrate that both sheep and porcine heparin and unfractionated heparin are comparable.

Sheep heparin provides an alternate source of heparin and low molecular weight heparins which is particularly suitable for the Muslim world for religious reasons. It is affordable and cost effective to produce sheep heparin and enoxaparin. Currently sheep heparin is under pre-clinical development and will soon undergo clinical validation. Thus sheep heparin will fill an unmet need not only for the Muslim world but will also provide an alternate source of heparin.