

International Aspirin Foundation



Senior Science Award Ceremony 2020

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Monday 16th November 2020

Venue: Virtual 2.00pm - 4.00pm GMT, UK 3.00pm - 5.00pm CET (GMT+1, EU) 10.00am - 12.00noon EDT (GMT-4, Boston, USA) 10.00pm - 12.00am CST (GMT+8, Shanghai & Singapore)





Welcome Pippa Hutchison Executive Director, IAF

In her welcoming speech, Pippa Hutchison, described aspirin's herbal roots in antiquity, its utility in medicine for over 120 years and its place today as a WHO globally essential drug which continues to grow and a ttract research interest across multiple disease areas including the current COVID-19 RECOVERY trial.

The International Aspirin Foundation (IAF), since its formation in 1974, has been a central resource for multidisciplinary collaboration. It has a Scientific Advisory Board (SAB) that guides its work to further our knowledge of aspirin and inspire ideas for the medical application of this versatile, inexpensive and accessible drug.

The IAF Senior Science Award recognises and honours exceptional scientists who have made an outstanding contribution to our knowledge and understanding of aspirin, Pippa paid tribute to Peter Sleight, an influential cardiologist and chair of the ISIS trial, who sadly died in October 2020. Peter was a recipient of the IAF Senior Science Award in 2000.

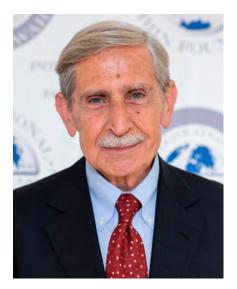
Pippa welcomed the winners of this year's award stating;

'I am very excited to hear from the trialists whose work immediately changed clinical practice across the globe, whilst their trials were on different patient groups, they showed the same effectiveness of low-dose aspirin in these different settings – certainly a magnificent achievement.'









Introduction Professor Carlo Patrono

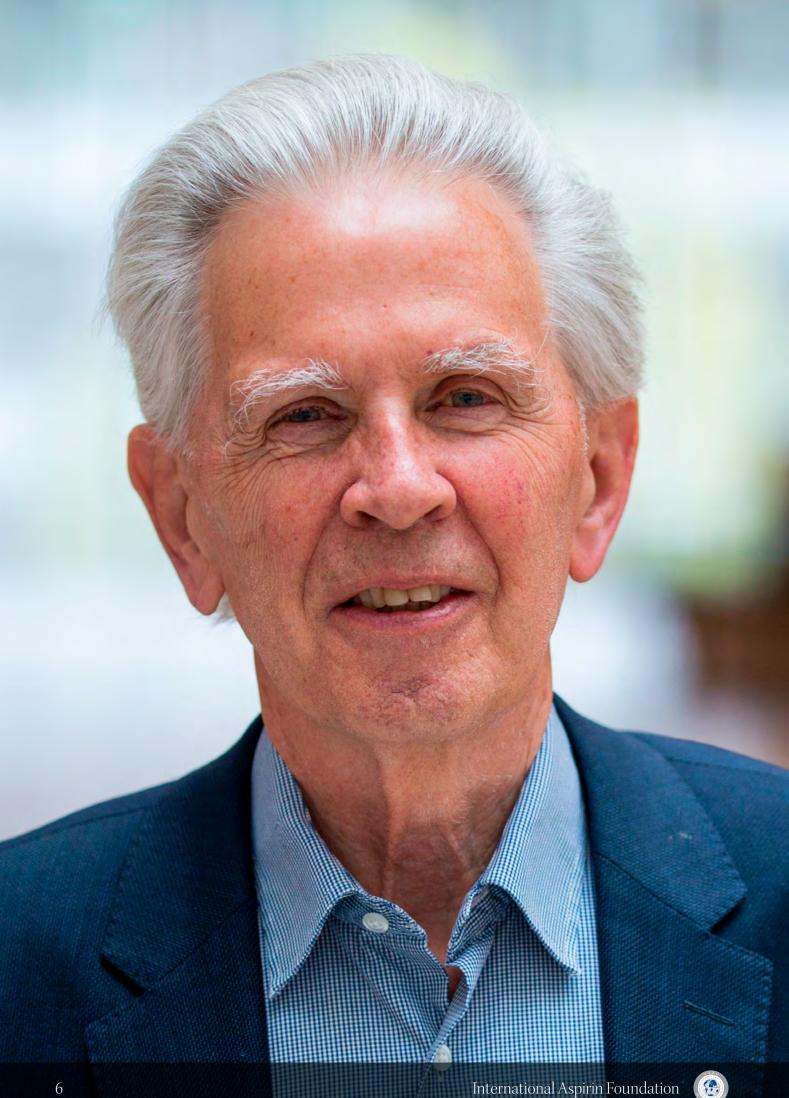
Chair, Scientific Advisory Board

Professor Carlo Patrono described his great respect, immense gratitude and profound admiration for the four awardees of the 2020 Senior Scientist Award. He explained how these physician scientists were responsible for the design of the very first low-dose aspirin trials given once daily for the prevention of coronary and cerebrovascular events. Lessons from these pioneering trials have not only established the role for low-dose aspirin in both cardiology and neurology, they also influenced the design of trials in other clinical settings. Recruitment into these trials took place in the mid to late 1980s at a time when much higher doses of aspirin were used with conflicting results in terms of efficacy and a substantial burden of gastrointestinal toxicity.

'It took intellectual courage as well as mechanistic insight to conceive the design of these four pivotal trials and convince the medical scientific community of the time that this was a scientifically sound and ethically justified exercise of clinical investigation.'

Professor Carlo Patrono







Awardee Presentations Professor Lars Wallentin

The RISC trial was the first trial to test the efficacy and safety of low-dose aspirin in unstable coronary disease which then became the corner stone of management in this setting. Professor Wallentin described how his research focus had been around using the increased scientific understanding of the pathophysiology of coronary artery disease to investigate the prognostic implications of ischemia and find ways to assess and treat it. An appreciation of coronary atherosclerosis, angina and unstable angina as dynamic events indicating coronary stenosis and plaque ruptures grew and it became clear these changes increased the risk of myocardial infarction (MI).

'it is the lesion that is unstable not the patient'

It was work by Professor Carlo Patrono explaining the science behind low-dose aspirin's use as an antiplatelet that inspired and influenced the design of the RISC trial. In his publication in Circulation in 1985, Carlo Patrono had concluded;

'whether a selective sparing of extra platelet cyclooxygenase activity by low-dose aspirin will result in increased antithrombotic efficacy, fewer toxic reactions, or both remains to be established in prospective clinical trials.'

The RISC trial randomised 800 men, with unstable coronary disease, to low-dose (75 mg once daily) aspirin or placebo. RISC measured MI and death during first the 3 months of treatment and showed a very dramatic 65 % reduction in event rate over the first month which was maintained over longer term follow up [p <0.0001 at 3 months]. The trial published in The Lancet in 1990, showed that the effect of low-dose aspirin was maintained at 1 year. Professor Wallentin explained the impact this result had;

'it was almost unbelievable to the investigators and ourselves to see that only 1/7th of a standard acetylsalicylic acid dose used for headache was so effective in patients with acute myocardial infarction.'

By comparing the different dosages used in varying trials it was possible to see that the 75 mg daily dose was at least as effective as higher doses, and this became the standard of care in patients with acute coronary syndrome (ACS) and has remained the recommended treatment for over 30 years.

The study also included the use of IV heparin over the first five days and this combination of antiplatelet plus anticoagulant was the most effective treatment in short term reduction in event rate, but this effect did not stay over time.

The FRISC-II study found that early invasive procedures as well as low-dose aspirin, and early anticoagulants, added a 25% further reduction in the risk of MI and death. This combination of low-dose aspirin and early invasive procedures then became the standard of care. Long term follow-up over 15 years has shown that this effect stays over time.

The group also carried out work to evaluate the role of troponin as a prognostic test. They found a prognostic signal coming from troponin with an increased event rate in those with raised troponin levels helping to show who has thrombosis and can respond to antithrombotic and antiplatelet therapy.



The Swedish registry shows the continuing development of antiplatelets for acute coronary syndrome over the last 25 years and tracks the developments in the medical treatment of ACS, with new antiplatelet drugs and new anticoagulants emerging onto the stage. The results of the Twilight trial in 2019, which evaluated if low-dose aspirin could be dropped from a Ticagrelor plus aspirin regimen, found that aspirin could be removed after 3months with a substantial reduction in bleeding events.

Questions

During the discussion, the issue with trying to intensify this effect from low-dose aspirin was debated. Attempts to intensify antithrombotic regimens have not been completely successful due to the difficulty in balancing ischaemic risk versus bleeding risk. Professor Wallentin felt that future work would be important to help identify tools that would help inform decisions around treatment intensity and the duration of combination antithrombotic therapy. Tools are needed to help identify which patients will benefit from different regimens.

'it should be based on selecting the treatment but also selecting the patients and we are using both clinical criteria and different biomarkers indicating risk of stroke, risk of ischaemia and risk of bleeding.'

The Twilight trial, and other new studies, only investigate dropping aspirin rather than the newer agents and the group agreed that research to investigate which treatment agent to drop over time would be optimal and that a trial, including cost effectiveness measures, with several arms dropping different agents and comparing the effects would be useful.





To watch Professor Lars Wallentin's presentation click here



Lars Wallentin

Lars Wallentin became the first Professor of Cardiology at Uppsala University Hospital, Uppsala, Sweden in 1991 and was Head of the Department of Cardiology from 1991 to 1999. In 1992 he started and became the first chairman of the Swedish Registry of Acute Cardiac Care (RIK-HIA). In 2001, he founded the Uppsala Clinical Research Center and was its first Director until 2008. Over the last 20 years he has been the chairman and principal investigator of many national and international clinical trials. The group of Professor Wallentin has developed many new concepts concerning pathogenesis, diagnosis, risk stratification, antithrombotic and interventional treatments in acute coronary artery disease and stroke prevention in atrial fibrillation where they have pioneered the use of molecular biomarkers for prognostication and decision support.

Professor Wallentin has published more than 700 papers in peer-reviewed international Journals with h-index 119 (Scopus) and more than 80,000 citations. He was the President of the Swedish Cardiac Society, and from 2000 to 2002, he founded and served as President of the Swedish Heart Association. He has also received several prestigious research awards and was in 2010 honored with the European Society of Cardiology Gold Medal for his outstanding contributions to the science and practice of cardiology.







Awardee Presentations Professor Bo Norrving



The Swedish Aspirin Low-Dose Trial (SALT) represented the first placebo-controlled study to show that low-dose (75 mg daily) aspirin was effective for secondary prevention after cerebrovascular ischemic events - a treatment that is still the standard of care today.

Professor Bo Norrving presented from a perspective gained during four decades of experience on his recollections and reflections. Professor Norrving described the stroke era before CT scans and preventative therapy. Patients with a transient ischemic attack (TIA) were sent home with no therapy, stroke patients over 65 were considered too old for rehabilitation, and overall stroke was viewed as a very low priority.

The idea behind this pivotal trial, which established the role of low-dose aspirin in stroke, was formed in 1982 at a meeting about recommendations by the Swedish Medical Products Agency. An awareness of prostaglandin research led to a need to scientifically test these laboratory findings in the clinic and establish the efficacy of low-dose aspirin for stroke prevention. The collaboration brought Swedish stroke neurologists, internists, pharmacologists and the Swedish Medical Products Agency together for the first time, which in a longer perspective had a profound effect in unifying Swedish professionals working with stroke.

'We were like political parties, we had very strong opinions in different aspects, and we had lengthy discussions and arguments about the set up and protocol.'

SALT included 1360 patients who had experienced TIA, minor stroke or retinal artery occlusion in the preceding 3 months, recruited from December 1984 to Jan 1989. Due to the debate the run-in period allowed optional therapy for 3-5 weeks. Patients were randomised to receive either aspirin 75 mg once daily or placebo. The study was successful and clearly showed significant benefits of using low-dose aspirin for stroke free survival over long term follow up.

Professor Norrving shared his memories of working late into the night on the manuscript, having taken home one of the first versions of the Mac portable and getting the acceptance letter from The Lancet (a rare immediate accept of the submitted manuscript) which then sparked a lot of media interest.

'We had the publication in The Lancet and looking back I think we were very naïve at that time that we didn't really recognise that this was an important study and I remember being at home with small children on my lap and the telephone started ringing from across the Atlantic from the newspapers in the USA asking if I could comment on this and we were totally unprepared we had no press release nothing like that we were not really professionally marketing the study.'

The SALT publication from 1991 was included, fifteen years later, in 'Vintage Papers From The Lancet' marking its important standing in medical history.

In 1994, the Swedish Stroke Register (Riksstroke) was set up creating the very first national stroke register in the world with all 72 stroke admitting hospitals participating and outcomes from stroke patients, including patient reported outcomes (PROMs) 3 and 12 months after having a stroke, were collected. Early indicators from 1996-1997 showed that 95% of people received a CT scan, 71% were cared for in a stroke unit, 90% received antiplatelets and 25% of those with atrial fibrillation (AF) and ischaemic stroke received anticoagulation.

Strong debate continued at stroke conferences and in publications for several years about the optimal antithrombotic therapies for stroke prevention and the



dose of aspirin to use. There was growing recognition of a conflict of interests and a feeling that this heated debate could be detracting attention away from other areas of stroke research

Working with Peter Rothwell, and other co-workers, it was possible to demonstrate, by combining trial data, that the most important effect of aspirin was seen very early after the onset of an ischemic event. This was an extremely significant finding and led to consideration that patients should self-administer aspirin for a suspected TIA even before coming to hospital.

Stroke is now on the global political agenda and Professor Norrving has been working with the World Health Organisation (WHO) and involved in their Global Action Plan (2013-2020) for the prevention and control of noncommunicable diseases (NCDs). Within its nine global targets are the goals to ensure at least 50% of eligible people receive drug therapy and counselling to help enable them to prevent heart attacks and stroke and that there is an 80% availability of the basic technologies and essential medicines that are required to treat major NCDs.

Professor Norrving reflected upon a remarkable period of acute and secondary preventative therapeutic advances with organised stroke care now taking place in dedicated stroke units, acute therapies including IV thrombolytic therapy, endovascular therapy, hemicraniectomy, and secondary prevention with carotid endarterectomy and stenting, antiplatelet therapy, anticoagulants for stroke with AF, NOACS, blood pressure lowering therapy and statins.

However, there is no time for complacency as despite this knowledge and advancement the PURE study published in The Lancet in 2011 showed that for many middle-income and low-income countries basic antiplatelets were unavailable or unaffordable; with only 27% on a long-term basis having access to antiplatelet therapy in lower-middle income countries and only 2% in low-income countries;

'we still have a very long way to go to make this basic therapy globally available.'

Questions

During the discussion time, the role of genetics in antiplatelet therapy was discussed but whilst acknowledging that this may be important Professor Norrving pointed out that the feasibility of using genetic testing will need to be demonstrated when we already have an effective and widely available drug.

When asked about gender and aspirin therapy for stroke Professor Norrving explained that whilst it took time to agree aspirin is effective for women as well and men.

Professor Norrving was asked why some neurologists could not accept that low-dose aspirin was effective and explained that those supporting higher doses felt that you can't rely on what you find in experimental data, there was a lot of debate on p values versus the confidence interval concept etc. The arguments over low-dose versus high-dose aspirin took place predominantly in the stroke rather than the cardiac arena, it was felt that the vessels in the brain were different and that you could not compare with cardiology. The turning point, in accepting low-dose aspirin for stroke therapy came at the end of the 1990s with the publications of the aspirin trialists collaboration which looked at all the available evidence.





To watch Professor Bo Norrving's presentation click here

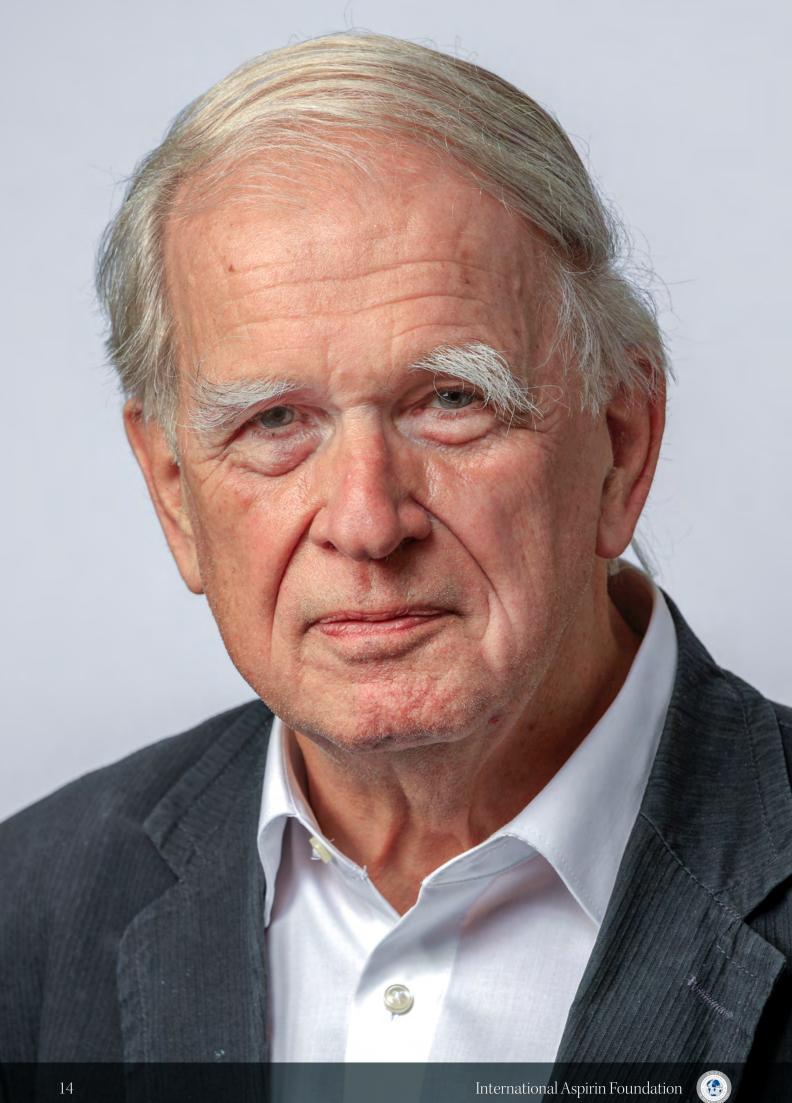


Bo Norrving

Bo Norrving is professor in neurology at Lund University, Sweden. He has published over 550 scientific articles and several books. His research activities have focused on clinical trials, stroke epidemiology, small vessel disease, clinical genetics, and organisation of stroke services.

He was corresponding author of the Swedish Aspirin Low-Dose Trial (SALT) published in 1991, and he has contributed to a large number of other pivotal clinical trials. He chaired the steering committee of SIFAP, the world's largest study on stroke in the young. He is a founder of the Swedish Stroke Register (Riksstroke), the world's 1st national stroke registry. He is Editor-in-Chief of the European Stroke Journal. He was President of the World Stroke Organization 2008 to 2012, and he has represented stroke at the WHO and the UN. Bo Norrving has played an important leadership role in raising the profile of stroke globally, and he has received several awards.





Awardee Presentations Professor Jan van Gijn



The Dutch TIA trial represented the first randomised trial comparing low-dose with higher dose aspirin in patients with cerebral vascular disease and showed the lowest daily dose necessary to completely suppress platelet thromboxane production is no less effective than higher doses and better tolerated after TIA or minor stroke. This provided important mechanistic data on how aspirin works to prevent major vascular events.

Professor Jan van Gijn began his presentation with an aerial photo of Utrecht in the Netherlands in 1986 where most of the work was done. He explained the knowledge of aspirin's mechanism of action in 1986, the time this trial was planned, was that aspirin prolonged bleeding time by inhibiting platelets and inactivating the enzyme cyclo-oxygenase.

Professor van Gijn used a cartoon diagram to explain how clinical neurologists, without a solid background in biochemistry, had to get acquainted with the science needed to understand aspirin's mode of action. This included the role of thromboxane A2. a substance that promotes platelet aggregation, and how aspirin diminishes the propensity of blood platelets to aggregate and form clots by irreversibly inactivating the cyclooxygenase molecule and to then apply this to the understanding of how a stroke or TIA occurs. Clot formation and embolization is a key factor in the pathogenesis of stroke with atherosclerosis developing on the wall of the vessel with subsequent clot formation. From this smaller or larger bits of the plaque can break off and get carried downstream to the brain causing a TIA or ischemic stroke.

In the meantime, a second action of aspirin was discovered, its role in endothelial cells with the production of prostacyclin. These cells are nucleated which means cyclooxygenase can be re—synthesised when it has been inactivated by for example aspirin and even more important in this cell the end product of the process by which cyclooxygenase is active is an antiaggregant substance – prostacyclin.

Aspirin therefore has a double barrel action blocking prostacyclin which inhibits platelet aggregation and thromboxane A 2 which promotes platelet aggregation and the answer clinically to this is in choosing a dose that spares endothelial prostacyclin whilst still blocking thromboxane A2. Research in the laboratory showed that 30 mg of aspirin daily spares endothelial prostacyclin while still completely blocking thromboxane A2 and prolonging bleeding time. The Dutch TIA trial aimed to test this dose in clinical practice

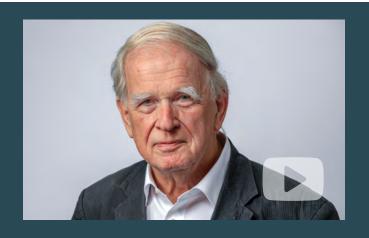
The Dutch TIA trial, carried out across 63 centres, included 3131 patients with TIA or non-disabling stroke occurring less than 3 months before recruitment and who were independent in activities of daily life. The participants were randomised to a daily aspirin dose of either 30 mg or the standard dose of 283 mg. The minimal follow-up period was 1 year with five years between the first patient and publication. The results published in the NEJM in 1991 showed an advantage from low-dose aspirin with this disappearing in the last few months of the trial. Side effects, minor bleeding, gastric discomfort and other minor adverse effects were reduced by 17% in the 30 mg dose. After 3 years of follow up however 15% of patients had still died or had a stroke so there was still some work to be done to further improve stroke prevention.



Questions

Professor van Gijn was asked if there was any evidence that because the 30 mg dose was better tolerated that patients were more compliant and that this concordance with the prescribed dose contributed to the favourable results in the 30 mg arm. He explained that this was not analysed but that it might have an effect and he agreed to ask a colleague if it would be possible to use the data to get an answer to that question.

Another question was if there are some patients, such as smokers, with a higher platelet turnover, who may need the dose or interval to be adjusted. This question was referred to Professor Patrono who explained that the duration of the antiplatelet effect with aspirin is strictly related to the rate of platelet turnover and that he was not aware of any specific studies examining this in the cerebrovascular field. However, there are studies from other clinical areas such as essential thrombocythemia, a rare blood cancer, with an accelerated rate of platelet turnover and therefore an accelerated renewal of the aspirin drug target. This work has shown that the antiplatelet effect of aspirin is shortened with most patients having incomplete platelet inhibition at 24 hours and therefore needing twice daily dosing to achieve platelet suppression. This effect has however been poorly investigated in other areas and needs further research.





To watch Professor Jan Van Gijn's presentation click here



Jan Van Gijn

J. van Gijn (1942) studied medicine in Leiden, The Netherlands. After a spell of social psychiatry during military service he was trained as a neurologist, at Rotterdam University Hospital and at the National Hospital, Queen Square (1971-1975).

He was awarded an MD for a thesis on 'The plantar reflex - a historical, clinical and electromyographic study' (Rotterdam, 1977).

From 1983 to 2007 he was professor and chairman of the department of Neurology of the University Medical Centre (UMCU) in Utrecht. His main research subject was cerebrovascular disease, ischaemic or haemorrhagic. Additional interests included somatization and the history of neurology. After his formal retirement he continued part-time clinical work for 5 years, at the outpatient department for neurology (UMCU).

He then pursued his historical interests by studying Latin (University of Amsterdam) and History and Philosophy of Science (Utrecht). He is currently writing a book on the history of stroke.





Awardee Presentations Professor Tom Meade



Given by Professor Peter Rothwell

Professor Tom Meade carried out seminal work in the 70s and early 80s on haemostasis particularly in acute coronary events and cardiac death. He showed repeatedly, in the Northwick Park Heart Study, that coagulation pathways were clearly important, especially factor VII, a vitamin k dependent clotting factor, which he showed to be a powerful risk factor for cardiac events (especially fatal events) in middle-aged high-risk men and that warfarin by reducing factor VII levels was useful in preventing events. This observation contributed to the setting up of the Thrombosis Prevention Trial (TPT) the first randomised trial of low-dose aspirin for the primary prevention of cardiovascular events specifically in high-risk men.

The TPT was a 2 by 2 factorial designed trial looking at essentially two novel treatments; low intensity warfarin with target INR of 1.5 and a novel controlled release formulation of low-dose aspirin. Professor Meade looked for a synergistic effect of combining anticoagulant and antiplatelet therapies. The controlled release formulation of aspirin offered more sustained levels with a 10-fold lower level at peak potentially preventing prostacyclin inhibition.

The trial showed a benefit of low-dose aspirin in reducing non-fatal coronary events, but low-dose aspirin did not reduce stroke or fatal MI. This pattern of effect was later confirmed by a metanalysis of the first six coronary heart disease (CHD) primary prevention trials. The results of TPT added to the evidence that low-dose aspirin reduces non-fatal ischemic heart disease (IHD) and that warfarin reduced all IHD due mainly to an effect on fatal events. Combined treatment with the antiplatelet and anticoagulant was more effective in reducing IHD than either agent on its own. This synergistic effect with aspirin and warfarin was offset to some extent by more bleeding in the combination arm. The trial was ahead of its time in that it identified patients by screening men in primary care practices to identify those with the highest (top 20%) cardiovascular risk. In total 10,000 high high-risk middle- aged men were identified and of these half agreed to be randomised. This was an unusually good recruitment from the target group giving the trial high external validity. The trial identified precisely the population it sought to find, men at high risk of IHD due to smoking, a family history of CHD, raised blood pressure, raised BMI, raised cholesterol, elevated fibrinogen and elevated factor VII.

Professor Meade continued to follow up the trial cohort after publication in 1998 and this was when his collaboration with Professor Peter Rothwell began due to Peter's interest in aspirin's potential role in the prevention of colorectal cancer (CRC) and some other cancers. Using long term follow-up data from earlier trials Professor Rothwell had found evidence of a delayed effect of aspirin on cancer but this came from trials where higher doses of aspirin had been used.

Professor Rothwell worked with Tom Meade and Bo Norrving to look at the 20-year risk of fatal CRC on long term follow up of low-dose aspirin trials in order to see if low-dose aspirin had the same effect on fatal CRC as seen in higher dose trials. In TPT, on its own, the result was statistically significant. It was also interesting in that TPT the factorial comparison helped to ensure that the reduction in risk wasn't an artefact of gastrointestinal bleeding leading to investigation and the identification of precancerous polyps. TPT showed no effect from warfarin on CRC deaths, despite an increase in bleeding, whereas there was an effect with aspirin. The effect of aspirin was very likely via its antiplatelet effect in the portal venous system and this helped add to the understanding of the mechanism by which aspirin was working. In addition, a hint of a reduction in oesophageal and lung cancer was seen and these post trial signals were available due to Professor Meade's long term follow up. It was also possible to investigate aspirin's effect on cancer metastasis due to detailed paper records Professor Meade had kept of all outcomes including fatal and non-fatal cancers. This gave convincing evidence that aspirin was associated in a reduced risk of distant metastasis.

Questions

During the question time Professor Rothwell described the ongoing work with aspirin and cancer, including working with various trialists to update some of the early analysis including follow up on the Physicians' Health Study (PHS) and Women's Health Study (WHS) of aspirin in primary disease prevention, and more recent trials such as the ARRIVE, JPPP, ASCEND and ASPREE to see if the early signals, short-term effects on in-trial cancer incidence or death are still visible.

When asked about aspirin dose for cancer, Professor Rothwell explained that TPT provides the most relevant data because in terms of systemic bioavailability it had the lowest dose of aspirin in all the trials studied and yet the effect of low-dose aspirin on cancer incidence and death was greatest in TPT. This makes it hard to argue that higher doses are required for a cancer effect given what was seen in TPT.





To watch Professor Peter Rothwell's presentation on behalf of Professor Tom Meade click here



Thomas W Meade

Professor Thomas W (Tom) Meade,FRS received his medical training at Christ Church, Oxford and then at Barts, qualifying in 1960. After a year working on aspects of leprosy in South India, he became Director of the Medical Research Council's Epidemiology and Medical Care Unit in 1970.

His personal interest has been the thrombotic component of coronary heart disease (CHD), for which he was elected Fellow of the Royal Society in 1996. He received the Balzan Prize for Epidemiology in 1997. At Northwick Park and Barts he was physician in charge of the thrombosis clinic. On his retirement from the MRC in 2001, he moved as Emeritus Professor of Epidemiology to the London School of Hygiene & Tropical Medicine, where he has continued working.

Professor Meade has published over 350 scientific papers, with an h-index of 86 and >37,000 citations (source, Scopus). He has been co-author of an overview of trials of aspirin in the primary prevention of coronary heart disease, showing that low-dose aspirin (75 mg daily) is as effective as higher doses with a lower risk of bleeding. The results of his and other trials of aspirin have also shown that it is valuable in reducing the incidence, metastasis and mortality of several cancers, principally of the large bowel.



Virtual award presentation ceremony

Professor Carlo Patrono presented each of the awardees with their certificates and engraved crystal, praising how their longstanding contributions have benefited health and disease prevention strategies. They also received an endowment of £5,000 each.

Professor Patrono paid tribute to the scientific courage, innovation, imagination and persistence that resulted from these exciting discoveries. The awardees collaborative working and integration of mechanistic scientific insights, with clinical observation, to develop vigorous trial designs and test pioneering concepts, has provided us with improved primary and secondary CVD prevention, as well as informing and improving clinical trial design.

Inspirational Pioneers

The International Aspirin Foundation was delighted to have the opportunity to formally recognise Professors Tom Meade, Jan van Gijn, Bo Norrving and Lars Wallentin, the scientists whose work established low-dose aspirin as a mainstay of antithrombotic therapy in the treatment and prevention of heart attack and stroke.

Investigation into low-dose aspirin's effectiveness for disease prevention remains an active and stimulating area for basic and clinical research.

The Senior Science Award ceremony was a chance to showcase this ground-breaking work, to benefit from the experience of hearing about the trials from the original Investigators, and to show our gratitude for the impact this work has had on Medicine today.





Senior Science Award kindly supported by Bayer AG

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